



Australian Government

Department of Health

Therapeutic Goods Administration

Database of Adverse Event Notifications - medicines

Medicine summary

You searched for the following **4 medicines** between **01/01/2020 – 13/08/2021**:

- COMIRNATY COVID-19 vaccine (BNT162b2 (mRNA))
- COVID-19 Vaccine (TNS) (COVID-19 Vaccine (Type not specified))
- COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector))
- Spikevax COVID-19 vaccine (Elasomeran (mRNA))

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Important information

The TGA uses adverse event reports to identify when a safety issue may be present. An adverse event report does not mean that the medicine is the cause of the adverse event. If you are experiencing an adverse event, or think you may be experiencing one, please seek advice from a health professional as soon as possible. The TGA strongly advises people taking prescription medicines not to change their medication regime without prior consultation with a health professional.

About the Database of Adverse Event Notifications (DAEN) - medicines

- The DAEN - medicines contains information from reports of adverse events that the TGA has received in relation to medicines including vaccines used in Australia.
- The DAEN - medicines does not contain all known safety information about a particular medicine. Please do not make an assessment about the safety of a medicine based on the information in the DAEN - medicines.

The TGA medicine safety monitoring program

More information about the DAEN - medicines and the TGA medicines safety monitoring program is available at:

- About the DAEN - medicines <<http://www.tga.gov.au/safety/daen-about.htm>>
- Medicines safety <<http://www.tga.gov.au/safety/information-medicines.htm>>

You are encouraged to report an adverse event suspected of being related to a medicine used in Australia. Reports of adverse events in relation to medicines and vaccines can be reported using the 'blue card' reporting form, by phone and online <<http://www.tga.gov.au/safety/problem.htm>>.

Other useful sources of information on Australian medicines

More information about a medicine is available from the Product Information (PI)

<<http://www.tga.gov.au/hp/information-medicines-pi.htm>> and Consumer Medicine Information (CMI)

<<http://www.tga.gov.au/consumers/information-medicines-cmi.htm>> leaflet or the labelling of the medicine. Australian Public Assessment Report for Prescription Medicines (AusPARs) <<http://www.tga.gov.au/industry/pm-auspar.htm>> for some prescription medicines, are also available from the TGA website. <<http://www.tga.gov.au>>

Your health professional can also provide help and assistance on how to use medicines.

Information on medicines used in Australia is available from NPS MedicineWise <<http://www.nps.org.au/>>.

About the release of this information

While reasonable care is taken to ensure that the information is an accurate record of the adverse events reported to the TGA, the TGA does not guarantee or warrant the accuracy, reliability, completeness or currency of the information or its usefulness in achieving any purpose.

To the fullest extent permitted by law, including but not limited to section 61A of the Therapeutic Goods Act 1989, the TGA will not be liable for any loss, damage, cost or expense incurred in or arising by reason of any person relying on this information.

Copyright restrictions apply to the DAEN - medicines <<http://www.tga.gov.au/about/website-copyright.htm>>.

Results

Number of reports (cases): 48352

(Multiple adverse events have been reported for some patients)

Number of cases with a single suspected medicine: 47658

(The TGA thinks there is a possibility that the medicine caused the adverse event)

Number of cases where death was a reported outcome: 459

(These reports of death may or may not have been a result of taking a medicine)

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Nervous system disorders	Headache	16843	16662	15
Musculoskeletal and connective tissue disorders	Myalgia	11366	11278	4
General disorders and administration site conditions	Pyrexia	9727	9630	10
General disorders and administration site conditions	Injection site reaction	7335	7278	3
Gastrointestinal disorders	Nausea	7101	7036	8
General disorders and administration site conditions	Chills	7005	6962	2
Nervous system disorders	Lethargy	6973	6939	9
General disorders and administration site conditions	Fatigue	6752	6662	12
Musculoskeletal and connective tissue disorders	Arthralgia	6639	6574	4
Nervous system disorders	Dizziness	4793	4740	3
Gastrointestinal disorders	Vomiting	2468	2444	27
Gastrointestinal disorders	Diarrhoea	2358	2335	5
Skin and subcutaneous tissue disorders	Rash	2285	2264	5
Gastrointestinal disorders	Abdominal pain	2219	2207	7
Respiratory, thoracic and mediastinal disorders	Dyspnoea	2195	2155	41
General disorders and administration site conditions	Injection site pain	2140	2113	1
Nervous system disorders	Paraesthesia	2094	2058	3
General disorders and administration site conditions	Malaise	1792	1767	24
General disorders and administration site conditions	Influenza like illness	1781	1757	6
Musculoskeletal and connective tissue disorders	Pain in extremity	1603	1568	6
General disorders and administration site conditions	Chest pain	1576	1551	12

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Blood and lymphatic system disorders	Lymphadenopathy	1447	1429	0
Respiratory, thoracic and mediastinal disorders	Cough	1184	1167	5
Skin and subcutaneous tissue disorders	Hyperhidrosis	1063	1047	1
General disorders and administration site conditions	Pain	991	974	3
Metabolism and nutrition disorders	Decreased appetite	962	952	11
Nervous system disorders	Syncope	961	947	5
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	941	932	0
Nervous system disorders	Presyncope	899	887	1
General disorders and administration site conditions	Chest discomfort	846	828	0
Cardiac disorders	Palpitations	845	835	2
Skin and subcutaneous tissue disorders	Pruritus	803	795	1
Cardiac disorders	Tachycardia	777	765	2
Vascular disorders	Deep vein thrombosis	755	727	14
Skin and subcutaneous tissue disorders	Urticaria	706	700	0
Psychiatric disorders	Insomnia	700	687	1
Vascular disorders	Hypertension	696	690	2
Respiratory, thoracic and mediastinal disorders	Pulmonary embolism	688	671	34
Investigations	Fibrin D dimer increased	655	631	18
Eye disorders	Vision blurred	613	597	2
Musculoskeletal and connective tissue disorders	Back pain	610	596	2
Nervous system disorders	Tremor	585	576	0
Nervous system disorders	Hypoaesthesia	562	555	0
Nervous system disorders	Migraine	558	541	0
General disorders and administration site conditions	Asthenia	501	494	4
Gastrointestinal disorders	Paraesthesia oral	494	488	0
Ear and labyrinth disorders	Vertigo	475	469	1
Infections and infestations	Herpes zoster	470	462	1
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	453	450	0

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Immune system disorders	Anaphylactic reaction	430	424	0
Vascular disorders	Flushing	420	417	0
General disorders and administration site conditions	Feeling abnormal	404	400	0
Gastrointestinal disorders	Abdominal pain upper	402	392	1
Injury, poisoning and procedural complications	Contusion	400	392	3
Musculoskeletal and connective tissue disorders	Muscle spasms	384	378	0
Musculoskeletal and connective tissue disorders	Neck pain	382	380	1
General disorders and administration site conditions	Injection site swelling	378	376	0
Blood and lymphatic system disorders	Thrombocytopenia	374	359	20
General disorders and administration site conditions	Feeling hot	374	367	0
General disorders and administration site conditions	Local reaction	369	369	0
Nervous system disorders	Dysgeusia	357	352	0
Investigations	Blood pressure increased	354	351	0
Respiratory, thoracic and mediastinal disorders	Epistaxis	331	321	4
Investigations	Heart rate increased	329	322	2
General disorders and administration site conditions	Concomitant disease aggravated	326	318	7
General disorders and administration site conditions	Peripheral swelling	325	315	2
Ear and labyrinth disorders	Tinnitus	304	291	0
Psychiatric disorders	Anxiety	301	299	0
Vascular disorders	Hot flush	294	293	0
Respiratory, thoracic and mediastinal disorders	Throat tightness	290	289	0
Respiratory, thoracic and mediastinal disorders	Throat irritation	289	286	0
Psychiatric disorders	Confusional state	279	273	7
Immune system disorders	Hypersensitivity	272	268	0
Skin and subcutaneous tissue disorders	Erythema	268	263	0
Skin and subcutaneous tissue disorders	Cold sweat	264	264	1

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
General disorders and administration site conditions	Swelling	263	256	0
Skin and subcutaneous tissue disorders	Rash pruritic	259	256	0
Reproductive system and breast disorders	Menstrual disorder	233	227	0
General disorders and administration site conditions	Feeling cold	228	226	1
General disorders and administration site conditions	Injection site erythema	225	223	0
Musculoskeletal and connective tissue disorders	Limb discomfort	224	220	0
Gastrointestinal disorders	Swollen tongue	220	220	0
Vascular disorders	Hypotension	220	211	12
Eye disorders	Eye pain	217	213	0
Musculoskeletal and connective tissue disorders	Musculoskeletal stiffness	214	210	0
Vascular disorders	Thrombosis	203	194	5
Musculoskeletal and connective tissue disorders	Muscular weakness	201	194	1
Gastrointestinal disorders	Lip swelling	200	200	0
Vascular disorders	Pallor	200	199	2
Injury, poisoning and procedural complications	Vaccination error	198	179	2
Eye disorders	Photophobia	196	191	0
Infections and infestations	Nasopharyngitis	196	194	2
General disorders and administration site conditions	Injection site discomfort	196	194	0
Nervous system disorders	Seizure	195	193	5
General disorders and administration site conditions	Gait disturbance	191	188	0
Nervous system disorders	Cerebrovascular accident	190	185	32
Cardiac disorders	Pericarditis	186	177	0
Nervous system disorders	Taste disorder	176	176	0
Eye disorders	Visual impairment	174	166	0
Infections and infestations	Lower respiratory tract infection	174	173	1
Skin and subcutaneous tissue disorders	Angioedema	165	163	0
Respiratory, thoracic and mediastinal disorders	Nasal congestion	164	164	0

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Respiratory, thoracic and mediastinal disorders	Wheezing	163	160	3
Skin and subcutaneous tissue disorders	Swelling face	162	161	0
General disorders and administration site conditions	Swelling face	162	161	0
Nervous system disorders	Balance disorder	159	156	0
Ear and labyrinth disorders	Ear pain	159	153	0
Infections and infestations	Sinusitis	159	158	0
Nervous system disorders	Somnolence	155	154	6
General disorders and administration site conditions	Injection site hypersensitivity	151	150	0
Nervous system disorders	Facial paralysis	149	147	1
Nervous system disorders	Bell's palsy	146	143	0
Vascular disorders	Thrombophlebitis superficial	145	141	0
Respiratory, thoracic and mediastinal disorders	Asthma	143	142	0
Respiratory, thoracic and mediastinal disorders	Dysphonia	140	138	0
Infections and infestations	Pneumonia	137	129	16
Gastrointestinal disorders	Dry mouth	136	136	0
Injury, poisoning and procedural complications	Fall	136	128	11
Respiratory, thoracic and mediastinal disorders	Pharyngeal swelling	131	127	0
General disorders and administration site conditions	Feeling of body temperature change	129	127	0
General disorders and administration site conditions	Injection site pruritus	128	128	0
General disorders and administration site conditions	Thirst	126	124	0
Nervous system disorders	Burning sensation	126	124	0
General disorders and administration site conditions	Injection site rash	126	124	0
Reproductive system and breast disorders	Heavy menstrual bleeding	126	123	0
Nervous system disorders	Disturbance in attention	125	124	0
Infections and infestations	Cellulitis	123	122	1
Nervous system disorders	Ageusia	120	118	1
Skin and subcutaneous tissue disorders	Petechiae	119	117	1

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Psychiatric disorders	Disorientation	119	117	2
Gastrointestinal disorders	Abdominal discomfort	118	112	0
Injury, poisoning and procedural complications	Adverse event following immunisation	117	112	105
Gastrointestinal disorders	Dysphagia	117	116	3
Skin and subcutaneous tissue disorders	Night sweats	107	107	1
Nervous system disorders	Neuralgia	107	103	0
Nervous system disorders	Loss of consciousness	104	102	8
Gastrointestinal disorders	Abdominal distension	98	95	1
Cardiac disorders	Atrial fibrillation	96	92	4
Nervous system disorders	Dysarthria	94	88	4
Musculoskeletal and connective tissue disorders	Joint swelling	93	89	0
General disorders and administration site conditions	Injection site bruising	92	91	0
Cardiac disorders	Myocardial infarction	88	87	19
Eye disorders	Ocular hyperaemia	88	84	0
Nervous system disorders	Guillain-Barre syndrome	87	79	3
General disorders and administration site conditions	Axillary pain	86	85	0
General disorders and administration site conditions	Extensive swelling of vaccinated limb	85	85	0
Respiratory, thoracic and mediastinal disorders	Productive cough	85	83	0
Gastrointestinal disorders	Mouth ulceration	83	81	0
Gastrointestinal disorders	Hypoaesthesia oral	81	81	0
Musculoskeletal and connective tissue disorders	Pain in jaw	80	78	0
Gastrointestinal disorders	Dyspepsia	80	79	0
Infections and infestations	Urinary tract infection	78	75	3
Nervous system disorders	Head discomfort	78	77	0
Reproductive system and breast disorders	Menstruation irregular	78	76	0
Cardiac disorders	Myocarditis	75	71	1
Skin and subcutaneous tissue disorders	Rash erythematous	73	71	0
Vascular disorders	Peripheral coldness	72	71	1
Investigations	Body temperature increased	72	72	0
Psychiatric disorders	Sleep disorder	70	69	0

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Gastrointestinal disorders	Retching	69	68	1
Investigations	Blood pressure decreased	69	68	1
Respiratory, thoracic and mediastinal disorders	Oropharyngeal discomfort	69	68	0
Eye disorders	Diplopia	68	65	0
Blood and lymphatic system disorders	Lymph node pain	68	68	0
Eye disorders	Eye swelling	67	66	0
Musculoskeletal and connective tissue disorders	Muscle twitching	67	66	0
Investigations	Troponin increased	67	64	0
Metabolism and nutrition disorders	Dehydration	66	64	1
Infections and infestations	Bronchitis	64	63	0
Respiratory, thoracic and mediastinal disorders	Dry throat	64	63	0
Renal and urinary disorders	Pollakiuria	64	62	0
Respiratory, thoracic and mediastinal disorders	Sneezing	64	62	0
Blood and lymphatic system disorders	Immune thrombocytopenia	63	59	2
General disorders and administration site conditions	Oedema peripheral	63	58	2
Investigations	Platelet count decreased	62	59	4
Nervous system disorders	Transient ischaemic attack	62	59	0
Infections and infestations	Upper respiratory tract infection	60	60	1
Nervous system disorders	Aphasia	60	58	1
General disorders and administration site conditions	Injection site mass	59	59	0
Ear and labyrinth disorders	Deafness	59	56	0
Infections and infestations	Oral herpes	58	57	0
Psychiatric disorders	Delirium	56	55	2
Reproductive system and breast disorders	Intermenstrual bleeding	56	54	0
General disorders and administration site conditions	Vaccination site reaction	54	54	0
Gastrointestinal disorders	Constipation	53	52	0
Psychiatric disorders	Hallucination	53	52	1
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	52	50	0
Eye disorders	Eye pruritus	51	49	0

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Cardiac disorders	Bradycardia	50	49	1
Infections and infestations	Laryngitis	50	50	0
Infections and infestations	Viral infection	50	50	0
Respiratory, thoracic and mediastinal disorders	Haemoptysis	50	50	0
Investigations	Blood glucose increased	49	45	0
Musculoskeletal and connective tissue disorders	Muscle tightness	48	46	0
Infections and infestations	Tonsillitis	47	47	0
Infections and infestations	Pharyngitis	47	47	0
Musculoskeletal and connective tissue disorders	Groin pain	47	47	1
General disorders and administration site conditions	Concomitant disease progression	46	41	29
Nervous system disorders	Amnesia	45	43	0
Reproductive system and breast disorders	Vaginal haemorrhage	45	45	0
Skin and subcutaneous tissue disorders	Sensitive skin	45	44	0
General disorders and administration site conditions	Inflammation	45	42	0
Respiratory, thoracic and mediastinal disorders	Sinus pain	44	44	0
Investigations	Oxygen saturation decreased	44	42	5
Nervous system disorders	Memory impairment	44	44	0
General disorders and administration site conditions	Injection site inflammation	44	44	0
Skin and subcutaneous tissue disorders	Blister	44	42	0
Cardiac disorders	Arrhythmia	44	42	1
Psychiatric disorders	Restlessness	44	43	0
Infections and infestations	Sepsis	44	43	11
Reproductive system and breast disorders	Dysmenorrhoea	43	41	0
Respiratory, thoracic and mediastinal disorders	Sinus congestion	43	43	0
Cardiac disorders	Cardiac arrest	43	40	28
Infections and infestations	Rhinitis	43	43	1
Nervous system disorders	Anosmia	42	40	1
Investigations	Heart rate irregular	40	39	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Renal and urinary disorders	Haematuria	40	40	2
General disorders and administration site conditions	Injected limb mobility decreased	40	38	0
Musculoskeletal and connective tissue disorders	Mobility decreased	39	39	0
Respiratory, thoracic and mediastinal disorders	Aphonia	39	37	0
Infections and infestations	Diverticulitis	39	39	0
Nervous system disorders	Cerebral venous sinus thrombosis	39	37	4
Respiratory, thoracic and mediastinal disorders	Pleuritic pain	38	36	0
General disorders and administration site conditions	Non-cardiac chest pain	38	38	0
Nervous system disorders	Demyelination	38	36	1
Eye disorders	Lacrimation increased	38	35	0
Renal and urinary disorders	Renal pain	38	38	0
Skin and subcutaneous tissue disorders	Rash maculo-papular	38	36	0
Cardiac disorders	Acute myocardial infarction	38	36	5
Skin and subcutaneous tissue disorders	Rash macular	37	35	0
Nervous system disorders	Ataxia	37	37	0
Musculoskeletal and connective tissue disorders	Joint stiffness	37	36	0
Investigations	C-reactive protein increased	37	37	0
Musculoskeletal and connective tissue disorders	Bone pain	36	36	0
Vascular disorders	Thrombophlebitis	36	35	0
Eye disorders	Blindness	35	33	0
Eye disorders	Eye irritation	35	34	0
Nervous system disorders	Unresponsive to stimuli	35	34	13
Skin and subcutaneous tissue disorders	Pain of skin	34	34	0
General disorders and administration site conditions	Tenderness	34	34	0
Musculoskeletal and connective tissue disorders	Bursitis	34	34	0
Nervous system disorders	Parosmia	34	31	0
Reproductive system and breast disorders	Breast pain	34	33	0
Eye disorders	Conjunctival haemorrhage	34	34	0

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Renal and urinary disorders	Urinary incontinence	34	34	1
Infections and infestations	Injection site cellulitis	34	34	0
Musculoskeletal and connective tissue disorders	Musculoskeletal discomfort	34	34	0
Infections and infestations	Influenza	33	33	0
Musculoskeletal and connective tissue disorders	Arthritis	33	30	0
Psychiatric disorders	Abnormal dreams	33	33	0
Nervous system disorders	Neuropathy peripheral	33	33	0
Gastrointestinal disorders	Gastroesophageal reflux disease	33	31	1
Nervous system disorders	Hemiparesis	33	32	1
Investigations	Blood pressure abnormal	32	32	1
General disorders and administration site conditions	Injection site nodule	32	32	0
General disorders and administration site conditions	Facial pain	32	31	0
Investigations	Liver function test abnormal	32	30	0
Skin and subcutaneous tissue disorders	Skin discolouration	31	29	0
Investigations	Weight decreased	31	30	1
Ear and labyrinth disorders	Hypoacusis	31	31	0
Skin and subcutaneous tissue disorders	Skin sensitisation	31	31	0
Nervous system disorders	Speech disorder	31	30	0
Reproductive system and breast disorders	Postmenopausal haemorrhage	31	30	0
Gastrointestinal disorders	Gingival bleeding	30	30	0
Psychiatric disorders	Panic attack	30	30	0
Investigations	Heparin-induced thrombocytopenia test positive	30	30	2
Psychiatric disorders	Agitation	30	29	1
General disorders and administration site conditions	Oedema	30	29	0
Skin and subcutaneous tissue disorders	Photosensitivity reaction	30	29	0
Gastrointestinal disorders	Rectal haemorrhage	29	29	1
Gastrointestinal disorders	Haematochezia	29	27	0
Nervous system disorders	Cognitive disorder	29	29	2
Eye disorders	Periorbital swelling	28	28	0
Infections and infestations	Ear infection	28	27	0

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Vascular disorders	Haematoma	27	26	0
Hepatobiliary disorders	Portal vein thrombosis	27	26	1
Infections and infestations	Conjunctivitis	27	27	0
Gastrointestinal disorders	Toothache	27	27	0
Investigations	Heart rate decreased	27	27	0
Nervous system disorders	Restless legs syndrome	27	26	0
Renal and urinary disorders	Incontinence	27	26	0
Ear and labyrinth disorders	Ear discomfort	27	26	0
Infections and infestations	Appendicitis	27	27	1
Infections and infestations	Gastroenteritis	26	24	0
General disorders and administration site conditions	Condition aggravated	26	25	0
Respiratory, thoracic and mediastinal disorders	Tachypnoea	26	26	2
Infections and infestations	Infection	26	26	1
Nervous system disorders	Cerebral infarction	26	26	3
Surgical and medical procedures	Hospitalisation	25	24	0
Psychiatric disorders	Depression	24	24	0
Vascular disorders	Orthostatic hypotension	24	24	0
Psychiatric disorders	Poor quality sleep	24	24	0
Investigations	Blood fibrinogen increased	24	23	0
Respiratory, thoracic and mediastinal disorders	Hypopnoea	24	23	1
Vascular disorders	Haemorrhage	24	22	2
Renal and urinary disorders	Chromaturia	24	24	0
Nervous system disorders	Poor quality sleep	24	24	0
Cardiac disorders	Cyanosis	23	22	5
Injury, poisoning and procedural complications	Chillblains	23	22	0
Reproductive system and breast disorders	Polymenorrhoea	23	23	0
Metabolism and nutrition disorders	Hyperglycaemia	23	23	0
Vascular disorders	Cyanosis	23	22	5
Renal and urinary disorders	Dysuria	23	22	0
Investigations	Blood urine present	23	23	1
Gastrointestinal disorders	Oral pain	23	23	0
Nervous system disorders	Dyskinesia	23	22	0

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Skin and subcutaneous tissue disorders	Rash papular	23	23	0
General disorders and administration site conditions	Injection site hypoaesthesia	22	22	0
Nervous system disorders	Electric shock sensation	22	22	0
Psychiatric disorders	Irritability	22	21	0
Pregnancy, puerperium and perinatal conditions	Abortion spontaneous	22	20	0
Cardiac disorders	Cardiac flutter	22	22	0
Renal and urinary disorders	Acute kidney injury	22	20	2
Gastrointestinal disorders	Flatulence	22	21	0
Psychiatric disorders	Nervousness	21	21	0
Metabolism and nutrition disorders	Gout	21	21	0
Cardiac disorders	Angina pectoris	21	20	0
Musculoskeletal and connective tissue disorders	Flank pain	21	20	0
Nervous system disorders	Tension headache	21	21	0
General disorders and administration site conditions	Injection site warmth	21	21	0
Infections and infestations	Respiratory tract infection	21	19	0
Psychiatric disorders	Depressed mood	21	19	0
Nervous system disorders	Neurological symptom	21	20	0
Psychiatric disorders	Nightmare	21	20	0
General disorders and administration site conditions	Vaccination site pain	21	21	0
Nervous system disorders	Cerebral haemorrhage	21	20	8
Ear and labyrinth disorders	Deafness unilateral	20	20	0
Respiratory, thoracic and mediastinal disorders	Pleural effusion	20	19	0
Nervous system disorders	Coordination abnormal	20	19	0
Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	20	19	0
Gastrointestinal disorders	Colitis	20	20	0
Skin and subcutaneous tissue disorders	Blood blister	20	20	1
Blood and lymphatic system disorders	Anaemia	20	19	1
Product issues	Product quality issue	20	20	0
Skin and subcutaneous tissue disorders	Rash vesicular	20	19	0

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Ear and labyrinth disorders	Ear congestion	20	19	0
Cardiac disorders	Pericardial effusion	19	19	0
Nervous system disorders	Depressed level of consciousness	19	19	5
Gastrointestinal disorders	Mouth swelling	19	19	0
Musculoskeletal and connective tissue disorders	Costochondritis	19	18	0
Nervous system disorders	Facial paresis	19	18	0
Nervous system disorders	Migraine with aura	19	19	0
General disorders and administration site conditions	Gait inability	18	17	0
Musculoskeletal and connective tissue disorders	Axillary mass	18	17	0
Investigations	Blood pressure ambulatory increased	18	18	0
Gastrointestinal disorders	Gingival pain	18	18	0
Blood and lymphatic system disorders	Neutropenia	18	15	0
Nervous system disorders	Hyperaesthesia	18	18	0
Eye disorders	Dry eye	18	17	0
Gastrointestinal disorders	Eructation	18	18	0
General disorders and administration site conditions	Injection site paraesthesia	18	18	0
Skin and subcutaneous tissue disorders	Eczema	18	18	0
Eye disorders	Ocular discomfort	17	16	0
Eye disorders	Vitreous floaters	17	17	0
Gastrointestinal disorders	Gastritis	17	17	0
Nervous system disorders	Paralysis	17	17	0
Eye disorders	Swelling of eyelid	17	17	0
Nervous system disorders	Ischaemic stroke	17	17	2
Ear and labyrinth disorders	Vertigo positional	17	17	0
Cardiac disorders	Cardiac disorder	17	13	0
Gastrointestinal disorders	Salivary hypersecretion	17	17	0
Skin and subcutaneous tissue disorders	Purpura	17	17	0
Respiratory, thoracic and mediastinal disorders	Pharyngeal paraesthesia	17	17	0
Investigations	Fibrin D dimer	17	17	0
Gastrointestinal disorders	Pancreatitis	17	17	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Gastrointestinal disorders	Abdominal pain lower	17	16	0
Gastrointestinal disorders	Oral discomfort	17	17	0
General disorders and administration site conditions	Injection site haemorrhage	17	17	0
Investigations	Pulse abnormal	16	16	0
Respiratory, thoracic and mediastinal disorders	Stridor	16	16	0
General disorders and administration site conditions	Sensation of foreign body	16	16	0
Skin and subcutaneous tissue disorders	Skin burning sensation	16	16	0
Skin and subcutaneous tissue disorders	Skin exfoliation	16	16	0
Investigations	Urine output increased	16	16	0
Skin and subcutaneous tissue disorders	Skin reaction	16	16	0
General disorders and administration site conditions	Injection site injury	16	16	0
Investigations	Respiratory rate increased	16	16	1
Skin and subcutaneous tissue disorders	Skin irritation	16	16	0
Renal and urinary disorders	Urinary retention	16	15	0
Vascular disorders	Lymphoedema	16	15	0
Nervous system disorders	Monoplegia	16	16	0
Respiratory, thoracic and mediastinal disorders	Hyperventilation	16	16	0
Injury, poisoning and procedural complications	Product administered at inappropriate site	16	16	0
Investigations	Heart rate abnormal	16	15	0
Metabolism and nutrition disorders	Hypoglycaemia	16	16	0
Nervous system disorders	Sciatica	15	14	0
Nervous system disorders	Dizziness postural	15	15	0
Respiratory, thoracic and mediastinal disorders	Pleurisy	15	15	0
Blood and lymphatic system disorders	Lymphadenitis	15	15	0
Skin and subcutaneous tissue disorders	Pityriasis rosea	15	14	0
Blood and lymphatic system disorders	Splenic infarction	15	15	2
Investigations	Platelet count increased	15	14	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Psychiatric disorders	Mood altered	15	14	0
Respiratory, thoracic and mediastinal disorders	Pneumonia aspiration	15	14	10
Investigations	Blood glucose decreased	15	15	1
Skin and subcutaneous tissue disorders	Ecchymosis	14	14	0
Investigations	Liver function test increased	14	12	0
Nervous system disorders	Trigeminal neuralgia	14	14	0
Renal and urinary disorders	Polyuria	14	14	0
Social circumstances	Bedridden	14	14	0
Respiratory, thoracic and mediastinal disorders	Hypoxia	14	14	1
Respiratory, thoracic and mediastinal disorders	Pulmonary infarction	14	12	0
Nervous system disorders	Sensory loss	14	13	0
Cardiac disorders	Atrial flutter	14	13	1
Eye disorders	Eye haemorrhage	14	14	1
Infections and infestations	Rhinovirus infection	14	14	0
Gastrointestinal disorders	Bowel movement irregularity	13	13	0
Musculoskeletal and connective tissue disorders	Polymyalgia rheumatica	13	13	0
Vascular disorders	Varicose vein	13	12	0
Gastrointestinal disorders	Haematemesis	13	13	2
Gastrointestinal disorders	Mouth haemorrhage	13	13	0
General disorders and administration site conditions	Feeling jittery	13	13	0
Nervous system disorders	Hypokinesia	13	13	0
Vascular disorders	Vasculitis	13	13	0
Cardiac disorders	Supraventricular tachycardia	13	11	0
General disorders and administration site conditions	Face oedema	13	13	0
Reproductive system and breast disorders	Pelvic pain	13	12	0
Respiratory, thoracic and mediastinal disorders	Bronchospasm	13	12	0
Skin and subcutaneous tissue disorders	Dry skin	13	13	0
Reproductive system and breast disorders	Menstruation delayed	13	13	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Respiratory, thoracic and mediastinal disorders	Respiratory failure	13	12	7
Cardiac disorders	Cardiac failure	13	13	3
Investigations	White blood cell count decreased	13	11	0
Nervous system disorders	Haemorrhage intracranial	13	12	5
General disorders and administration site conditions	Nodule	13	13	0
General disorders and administration site conditions	Ulcer	13	12	0
Gastrointestinal disorders	Glossodynia	12	12	0
Musculoskeletal and connective tissue disorders	Rheumatoid arthritis	12	12	0
Immune system disorders	Anaphylactic shock	12	12	0
Nervous system disorders	Tunnel vision	12	12	0
Gastrointestinal disorders	Visceral venous thrombosis	12	11	2
General disorders and administration site conditions	Multiple organ dysfunction syndrome	12	12	7
Skin and subcutaneous tissue disorders	Dermatitis allergic	12	12	0
Reproductive system and breast disorders	Breast tenderness	12	11	0
Nervous system disorders	Generalised tonic-clonic seizure	12	10	1
Respiratory, thoracic and mediastinal disorders	Pulmonary pain	12	12	0
Eye disorders	Retinal vein occlusion	12	11	0
General disorders and administration site conditions	Discomfort	12	11	0
Respiratory, thoracic and mediastinal disorders	Tonsillar hypertrophy	11	11	0
Gastrointestinal disorders	Mesenteric vein thrombosis	11	10	1
Injury, poisoning and procedural complications	Product administration error	11	10	0
Musculoskeletal and connective tissue disorders	Trismus	11	11	0
Renal and urinary disorders	Nephrolithiasis	11	11	0
Vascular disorders	Vasodilatation	11	11	0
Infections and infestations	Vestibular neuronitis	11	11	0
Gastrointestinal disorders	Oral mucosal blistering	11	11	0
Nervous system disorders	Altered state of consciousness	11	10	1
Psychiatric disorders	Suicidal ideation	11	10	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Eye disorders	Visual field defect	11	11	0
Respiratory, thoracic and mediastinal disorders	Pulmonary congestion	11	10	1
Ear and labyrinth disorders	Hyperacusis	11	10	0
General disorders and administration site conditions	General physical health deterioration	11	10	10
Musculoskeletal and connective tissue disorders	Periarthritis	11	11	0
Blood and lymphatic system disorders	Coagulopathy	11	10	0
Cardiac disorders	Cardiomegaly	11	9	1
Vascular disorders	Blood pressure fluctuation	11	11	0
Musculoskeletal and connective tissue disorders	Fibromyalgia	11	11	0
Nervous system disorders	Visual field defect	11	11	0
Musculoskeletal and connective tissue disorders	Musculoskeletal pain	10	10	0
Cardiac disorders	Sinus tachycardia	10	9	0
Vascular disorders	Raynaud's phenomenon	10	10	0
Psychiatric disorders	Emotional distress	10	10	0
Psychiatric disorders	Hallucination, visual	10	10	0
Reproductive system and breast disorders	Oligomenorrhoea	10	10	0
Psychiatric disorders	Stress	10	10	0
Eye disorders	Eyelid ptosis	10	10	0
General disorders and administration site conditions	Hypothermia	10	10	3
General disorders and administration site conditions	Mass	10	10	0
Nervous system disorders	Tonic clonic movements	10	10	0
Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	10	10	0
Respiratory, thoracic and mediastinal disorders	Pulmonary oedema	10	10	1
Vascular disorders	Venous thrombosis	10	9	0
Cardiac disorders	Extrasystoles	10	10	0
Eye disorders	Asthenopia	10	10	0
General disorders and administration site conditions	Crying	10	10	0
General disorders and administration site conditions	Feeling drunk	10	10	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Immune system disorders	Seasonal allergy	10	10	1
Infections and infestations	Injection site infection	10	10	0
Skin and subcutaneous tissue disorders	Psoriasis	10	9	0
Infections and infestations	Herpes simplex	10	10	0
Skin and subcutaneous tissue disorders	Dermatitis	10	10	0
Gastrointestinal disorders	Anal incontinence	10	10	0
Gastrointestinal disorders	Faeces discoloured	10	9	0
General disorders and administration site conditions	Death	10	10	10
Eye disorders	Uveitis	10	9	0
Gastrointestinal disorders	Stomatitis	10	10	0
General disorders and administration site conditions	No adverse event	10	10	0
Injury, poisoning and procedural complications	Product administered to patient of inappropriate age	10	10	0
Metabolism and nutrition disorders	Hyponatraemia	10	10	0
Gastrointestinal disorders	Aphthous ulcer	9	9	0
Investigations	Body temperature decreased	9	9	1
Metabolism and nutrition disorders	Fluid retention	9	8	0
Respiratory, thoracic and mediastinal disorders	Pulmonary thrombosis	9	9	2
Gastrointestinal disorders	Reflux gastritis	9	9	0
Injury, poisoning and procedural complications	Eye contusion	9	9	0
Nervous system disorders	Muscle contractions involuntary	9	9	0
Nervous system disorders	Optic neuritis	9	9	0
Infections and infestations	Eye infection	9	8	0
Investigations	Coma scale abnormal	9	8	3
Infections and infestations	Candida infection	9	9	0
Nervous system disorders	Allodynia	9	9	0
Vascular disorders	Giant cell arteritis	9	9	0
Vascular disorders	Jugular vein thrombosis	9	9	0
Ear and labyrinth disorders	Eustachian tube obstruction	9	9	0
Gastrointestinal disorders	Tongue ulceration	9	9	0
Nervous system disorders	Drooling	9	8	0
Eye disorders	Blepharospasm	9	9	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Skin and subcutaneous tissue disorders	Cutaneous vasculitis	9	9	0
Investigations	Troponin abnormal	9	9	0
Nervous system disorders	Mental impairment	9	9	0
Psychiatric disorders	Affect lability	9	9	0
Gastrointestinal disorders	Gastrointestinal haemorrhage	9	9	2
Nervous system disorders	Incoherent	9	9	1
Cardiac disorders	Coronary artery disease	9	8	4
Eye disorders	Periorbital oedema	9	9	0
General disorders and administration site conditions	Exercise tolerance decreased	9	9	0
Respiratory, thoracic and mediastinal disorders	Respiratory distress	9	9	1
Investigations	Myocardial strain	9	9	0
General disorders and administration site conditions	Injection site urticaria	9	9	0
Renal and urinary disorders	Micturition urgency	9	9	0
Reproductive system and breast disorders	Amenorrhoea	9	8	0
Respiratory, thoracic and mediastinal disorders	Respiratory symptom	8	8	0
Infections and infestations	Abscess	8	6	0
Infections and infestations	Cystitis	8	8	0
Investigations	Troponin normal	8	7	0
Metabolism and nutrition disorders	Diabetes mellitus	8	8	1
Nervous system disorders	Myoclonus	8	8	0
Nervous system disorders	Nystagmus	8	8	0
General disorders and administration site conditions	Shoulder injury related to vaccine administration	8	8	0
Investigations	Troponin I increased	8	7	0
Investigations	White blood cell count increased	8	8	0
Renal and urinary disorders	Renal impairment	8	8	0
Musculoskeletal and connective tissue disorders	Spinal pain	8	8	0
Investigations	Blood glucose abnormal	8	8	0
Skin and subcutaneous tissue disorders	Alopecia	8	8	0
Gastrointestinal disorders	Colitis ischaemic	8	7	0
Gastrointestinal disorders	Frequent bowel movements	8	8	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Nervous system disorders	Nervous system disorder	8	8	0
Nervous system disorders	Superior sagittal sinus thrombosis	8	7	0
Vascular disorders	Vascular pain	8	8	0
Hepatobiliary disorders	Hepatitis	8	8	0
Vascular disorders	Embolism	8	8	1
Endocrine disorders	Hyperthyroidism	8	8	0
Investigations	Blood pressure systolic increased	8	8	0
Investigations	Electrocardiogram abnormal	8	7	0
Nervous system disorders	Dysaesthesia	8	7	0
Nervous system disorders	Dysstasia	8	8	0
Skin and subcutaneous tissue disorders	Acne	8	8	0
Cardiac disorders	Ventricular extrasystoles	8	8	0
General disorders and administration site conditions	No reaction on previous exposure to drug	8	8	0
Infections and infestations	Bacterial infection	8	8	0
Injury, poisoning and procedural complications	Subarachnoid haemorrhage	8	8	2
Nervous system disorders	Subarachnoid haemorrhage	8	8	2
Gastrointestinal disorders	Hyperaesthesia teeth	7	7	0
Nervous system disorders	Hemiplegia	7	7	0
Nervous system disorders	Multiple sclerosis	7	7	0
Metabolism and nutrition disorders	Hypophagia	7	6	3
Skin and subcutaneous tissue disorders	Vasculitic rash	7	7	0
Cardiac disorders	Postural orthostatic tachycardia syndrome	7	6	0
Investigations	Fibrin D dimer normal	7	6	0
Investigations	International normalised ratio increased	7	5	1
Eye disorders	Retinal artery occlusion	7	6	0
Gastrointestinal disorders	Gingival swelling	7	7	0
Injury, poisoning and procedural complications	Incorrect route of product administration	7	6	0
Skin and subcutaneous tissue disorders	Erythema multiforme	7	7	0
Gastrointestinal disorders	Tongue pruritus	7	7	0
Hepatobiliary disorders	Cholelithiasis	7	7	0
Psychiatric disorders	Euphoric mood	7	7	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Renal and urinary disorders	Renal failure	7	6	1
Infections and infestations	Encephalitis	7	7	1
Investigations	Lymph node palpable	7	7	0
Musculoskeletal and connective tissue disorders	Neck mass	7	7	1
Psychiatric disorders	Thinking abnormal	7	6	0
Respiratory, thoracic and mediastinal disorders	Paranasal sinus discomfort	7	7	0
Blood and lymphatic system disorders	Thrombocytosis	7	6	0
Ear and labyrinth disorders	Deafness neurosensory	7	7	0
Gastrointestinal disorders	Intestinal obstruction	7	7	1
Cardiac disorders	Atrial tachycardia	7	7	0
Musculoskeletal and connective tissue disorders	Tendonitis	7	7	0
Psychiatric disorders	Listless	7	6	0
Vascular disorders	Infarction	7	7	2
Eye disorders	Mydriasis	7	7	1
Gastrointestinal disorders	Tongue discomfort	7	7	0
Investigations	Red blood cell sedimentation rate increased	7	7	0
Cardiac disorders	Sinus bradycardia	7	7	0
Eye disorders	Photopsia	7	7	0
Gastrointestinal disorders	Oral pruritus	7	7	0
Nervous system disorders	Aura	7	7	0
Blood and lymphatic system disorders	Lymphopenia	6	4	0
Investigations	Blood test abnormal	6	6	0
Eye disorders	Vitreous detachment	6	6	0
Gastrointestinal disorders	Abnormal faeces	6	6	0
Gastrointestinal disorders	Lip ulceration	6	6	0
Investigations	International normalised ratio decreased	6	6	0
Musculoskeletal and connective tissue disorders	Systemic lupus erythematosus	6	6	0
Nervous system disorders	Nerve compression	6	6	0
Skin and subcutaneous tissue disorders	Skin warm	6	6	0
Nervous system disorders	Sinus headache	6	6	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Nervous system disorders	Transient global amnesia	6	6	0
Renal and urinary disorders	Nocturia	6	6	0
Respiratory, thoracic and mediastinal disorders	Pharyngeal hypoaesthesia	6	4	0
Gastrointestinal disorders	Faecaloma	6	5	0
Infections and infestations	Furuncle	6	6	0
Investigations	Haemoglobin decreased	6	5	0
Infections and infestations	Urosepsis	6	6	2
Investigations	Weight increased	6	5	0
Nervous system disorders	Haemorrhagic stroke	6	6	0
Gastrointestinal disorders	Gastrointestinal disorder	6	6	0
General disorders and administration site conditions	Injection site movement impairment	6	6	0
Musculoskeletal and connective tissue disorders	Temporomandibular joint syndrome	6	6	0
Nervous system disorders	Occipital neuralgia	6	6	0
Nervous system disorders	Tonic convulsion	6	6	0
Reproductive system and breast disorders	Breast swelling	6	6	0
Respiratory, thoracic and mediastinal disorders	Respiratory disorder	6	6	0
Vascular disorders	Aneurysm	6	6	1
Eye disorders	Eye disorder	6	6	0
Gastrointestinal disorders	Abdominal rigidity	6	6	1
Infections and infestations	Gingivitis	6	6	0
Injury, poisoning and procedural complications	Inappropriate schedule of product administration	6	5	0
Product issues	Product contamination physical	6	6	0
Skin and subcutaneous tissue disorders	Skin swelling	6	6	0
Cardiac disorders	Myocardial ischaemia	6	4	4
General disorders and administration site conditions	Drug ineffective	6	3	0
General disorders and administration site conditions	Vaccination site movement impairment	6	6	0
Infections and infestations	Ophthalmic herpes zoster	6	6	0
Injury, poisoning and procedural complications	Muscle strain	6	6	0
Endocrine disorders	Thyroiditis	6	6	0
Gastrointestinal disorders	Intestinal ischaemia	6	6	3

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Respiratory, thoracic and mediastinal disorders	Pharyngeal oedema	6	6	0
Respiratory, thoracic and mediastinal disorders	Tonsillar inflammation	6	6	0
Cardiac disorders	Cardiac failure congestive	6	6	0
Gastrointestinal disorders	Gastrointestinal pain	6	6	0
General disorders and administration site conditions	Sluggishness	6	6	0
Musculoskeletal and connective tissue disorders	Rhabdomyolysis	6	6	0
Renal and urinary disorders	Haemorrhage urinary tract	6	6	0
Renal and urinary disorders	Urine abnormality	6	6	0
Gastrointestinal disorders	Abdominal tenderness	6	6	1
General disorders and administration site conditions	Facial discomfort	6	6	0
Infections and infestations	Atypical pneumonia	6	6	0
Nervous system disorders	Seizure like phenomena	6	6	0
Psychiatric disorders	Abnormal behaviour	6	5	0
Eye disorders	Retinal detachment	6	6	0
Cardiac disorders	Arteriosclerosis coronary artery	5	5	4
General disorders and administration site conditions	Illness	5	5	0
Infections and infestations	Herpes zoster reactivation	5	4	0
Metabolism and nutrition disorders	Diabetic ketoacidosis	5	5	1
Nervous system disorders	Carpal tunnel syndrome	5	5	0
Reproductive system and breast disorders	Erectile dysfunction	5	5	0
Cardiac disorders	Cardiogenic shock	5	5	1
Gastrointestinal disorders	Glossitis	5	5	0
Gastrointestinal disorders	Pancreatitis acute	5	5	1
Infections and infestations	Mastitis	5	5	0
Infections and infestations	Severe acute respiratory syndrome	5	5	0
Nervous system disorders	Vlth nerve paralysis	5	4	0
Psychiatric disorders	Dysphemia	5	5	0
Psychiatric disorders	Emotional disorder	5	5	0
Respiratory, thoracic and mediastinal disorders	Apnoea	5	5	0
Respiratory, thoracic and mediastinal disorders	Sputum discoloured	5	5	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
General disorders and administration site conditions	Suprapubic pain	5	5	0
Infections and infestations	Varicella	5	5	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	5	5	0
Nervous system disorders	Febrile convulsion	5	5	0
Nervous system disorders	Intracranial pressure increased	5	5	1
Nervous system disorders	Sensory disturbance	5	5	0
Eye disorders	Eye discharge	5	5	0
Gastrointestinal disorders	Gastric ulcer	5	5	0
Immune system disorders	Drug hypersensitivity	5	5	0
Infections and infestations	Herpes zoster oticus	5	5	0
Reproductive system and breast disorders	Breast mass	5	5	0
Vascular disorders	Poor peripheral circulation	5	5	0
Eye disorders	Abnormal sensation in eye	5	5	0
General disorders and administration site conditions	Injection site discolouration	5	5	0
General disorders and administration site conditions	Pre-existing disease	5	5	0
General disorders and administration site conditions	Vaccination site swelling	5	5	0
Infections and infestations	Parainfluenzae virus infection	5	4	1
Investigations	Blood creatine phosphokinase increased	5	5	0
Nervous system disorders	Hypersomnia	5	5	0
Psychiatric disorders	Disorganised speech	5	5	0
Respiratory, thoracic and mediastinal disorders	Upper-airway cough syndrome	5	5	0
Eye disorders	Eyelid oedema	5	5	0
Infections and infestations	Genital herpes	5	5	0
Nervous system disorders	Cluster headache	5	5	0
Blood and lymphatic system disorders	Splenomegaly	5	3	0
General disorders and administration site conditions	Disease progression	5	5	3
Infections and infestations	Labyrinthitis	5	5	0
Infections and infestations	Sweating fever	5	5	0
Gastrointestinal disorders	Lip blister	5	5	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
General disorders and administration site conditions	Hunger	5	4	0
General disorders and administration site conditions	Vaccination site rash	5	5	0
Hepatobiliary disorders	Hepatic failure	5	5	2
Infections and infestations	Septic shock	5	5	3
Investigations	Heparin-induced thrombocytopenia test	5	5	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Neoplasm malignant	5	5	0
Nervous system disorders	Muscle spasticity	5	3	0
Nervous system disorders	Myelitis transverse	5	5	0
Respiratory, thoracic and mediastinal disorders	Throat clearing	5	5	0
Vascular disorders	Peripheral ischaemia	5	4	1
Gastrointestinal disorders	Diarrhoea haemorrhagic	5	5	0
Hepatobiliary disorders	Cholecystitis	5	5	0
Infections and infestations	Meningitis	5	5	1
Injury, poisoning and procedural complications	Exposure via breast milk	5	5	0
Metabolism and nutrition disorders	Polydipsia	5	5	0
Reproductive system and breast disorders	Adnexa uteri pain	5	5	0
Skin and subcutaneous tissue disorders	Skin tightness	5	5	0
Ear and labyrinth disorders	Ear haemorrhage	5	5	0
Ear and labyrinth disorders	Vestibular disorder	5	5	0
Eye disorders	Eye inflammation	5	5	0
Infections and infestations	Folliculitis	5	5	0
Injury, poisoning and procedural complications	Subdural haematoma	5	4	1
Injury, poisoning and procedural complications	Subdural haemorrhage	5	5	1
Investigations	Hepatic enzyme increased	5	5	0
Nervous system disorders	Fine motor skill dysfunction	5	5	0
Cardiac disorders	Cardiomyopathy	5	5	0
Gastrointestinal disorders	Epigastric discomfort	5	5	0
Respiratory, thoracic and mediastinal disorders	Respiratory arrest	5	4	1

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Blood and lymphatic system disorders	Heparin-induced thrombocytopenia	4	3	1
Cardiac disorders	Acute coronary syndrome	4	4	0
General disorders and administration site conditions	Secretion discharge	4	4	0
Injury, poisoning and procedural complications	Nerve injury	4	4	0
Investigations	Neutrophil count decreased	4	3	0
Reproductive system and breast disorders	Ovarian cyst	4	4	0
Respiratory, thoracic and mediastinal disorders	Aspiration	4	4	2
Respiratory, thoracic and mediastinal disorders	Pneumonitis	4	4	0
Infections and infestations	Bronchitis viral	4	4	0
Infections and infestations	Kidney infection	4	4	0
Investigations	Blood glucagon increased	4	4	0
Nervous system disorders	Cerebral thrombosis	4	4	0
Psychiatric disorders	Dissociation	4	4	0
Respiratory, thoracic and mediastinal disorders	Respiration abnormal	4	4	0
Ear and labyrinth disorders	Motion sickness	4	4	0
Eye disorders	Retinal vein thrombosis	4	4	0
Eye disorders	Visual acuity reduced	4	4	0
General disorders and administration site conditions	Temperature intolerance	4	4	0
Hepatobiliary disorders	Jaundice	4	4	0
Infections and infestations	Rash pustular	4	4	0
Investigations	Blood lactic acid increased	4	4	0
Metabolism and nutrition disorders	Metabolic alkalosis	4	4	0
Respiratory, thoracic and mediastinal disorders	Pulmonary mass	4	4	0
Infections and infestations	Skin infection	4	4	0
Musculoskeletal and connective tissue disorders	Synovial cyst	4	4	0
Nervous system disorders	Partial seizures	4	3	0
Psychiatric disorders	Bradyphrenia	4	4	0
Psychiatric disorders	Fear	4	4	0
Respiratory, thoracic and mediastinal disorders	Hiccups	4	4	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Respiratory, thoracic and mediastinal disorders	Pulmonary hypertension	4	3	1
Ear and labyrinth disorders	Ear swelling	4	4	0
Gastrointestinal disorders	Epiploic appendagitis	4	4	0
Gastrointestinal disorders	Lip dry	4	4	0
Infections and infestations	Gastrointestinal infection	4	3	0
Infections and infestations	Localised infection	4	4	0
Infections and infestations	Oral candidiasis	4	4	0
Infections and infestations	Otitis media	4	4	0
Infections and infestations	Tooth infection	4	4	0
Nervous system disorders	Hypogeusia	4	3	0
Nervous system disorders	Movement disorder	4	4	1
Psychiatric disorders	Anger	4	4	0
Psychiatric disorders	Panic reaction	4	4	0
Renal and urinary disorders	Renal infarct	4	4	0
Respiratory, thoracic and mediastinal disorders	Rales	4	4	0
Blood and lymphatic system disorders	Disseminated intravascular coagulation	4	4	1
Gastrointestinal disorders	Lip pain	4	4	0
General disorders and administration site conditions	Crepitations	4	4	0
Investigations	Blood iron decreased	4	4	0
Metabolism and nutrition disorders	Iron deficiency	4	4	0
Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	4	4	0
Nervous system disorders	Embolic stroke	4	4	0
Nervous system disorders	Hypotonia	4	4	0
Nervous system disorders	Post herpetic neuralgia	4	4	0
Skin and subcutaneous tissue disorders	Rash morbilliform	4	4	0
Social circumstances	Impaired driving ability	4	4	0
Gastrointestinal disorders	Anaesthesia oral	4	4	0
Gastrointestinal disorders	Haemorrhoids	4	4	0
Nervous system disorders	Clumsiness	4	4	0
Respiratory, thoracic and mediastinal disorders	Sinus disorder	4	4	0
Vascular disorders	Ischaemia	4	4	1

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Cardiac disorders	Cardiac ventricular thrombosis	4	4	1
Infections and infestations	Staphylococcal infection	4	4	1
Investigations	Cardiac monitoring	4	4	0
Investigations	Electrocardiogram ST segment elevation	4	4	0
Musculoskeletal and connective tissue disorders	Polyarthritis	4	4	0
Nervous system disorders	Formication	4	4	0
Nervous system disorders	Thrombotic stroke	4	4	1
Reproductive system and breast disorders	Suppressed lactation	4	4	0
Skin and subcutaneous tissue disorders	Skin mass	4	4	0
Eye disorders	Eye movement disorder	4	4	0
Gastrointestinal disorders	Proctalgia	4	4	0
Infections and infestations	Varicella zoster virus infection	4	4	0
Investigations	Blood glucose fluctuation	4	4	0
Metabolism and nutrition disorders	Fluid overload	4	3	0
Metabolism and nutrition disorders	Food craving	4	4	0
Nervous system disorders	Hemianopia	4	4	0
Psychiatric disorders	Delirium febrile	4	4	0
Respiratory, thoracic and mediastinal disorders	Pulmonary fibrosis	4	4	1
Skin and subcutaneous tissue disorders	Miliaria	4	4	0
Skin and subcutaneous tissue disorders	Skin discomfort	4	4	0
Vascular disorders	Aortic aneurysm rupture	4	3	4
Vascular disorders	Aortic dissection	4	4	0
Eye disorders	Eye oedema	4	4	0
Gastrointestinal disorders	Colitis ulcerative	4	4	0
Gastrointestinal disorders	Odynophagia	4	4	0
Investigations	Blood fibrinogen decreased	4	4	1
Metabolism and nutrition disorders	Increased appetite	4	4	0
Musculoskeletal and connective tissue disorders	Limb mass	4	4	0
Nervous system disorders	Lacunar infarction	4	4	0
Psychiatric disorders	Mood swings	4	4	0
Cardiac disorders	Cardiac discomfort	4	4	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
General disorders and administration site conditions	Injection site vesicles	4	4	0
Immune system disorders	Anaphylactoid reaction	4	4	0
Injury, poisoning and procedural complications	Ankle fracture	4	4	0
Investigations	Blood test normal	4	4	0
Investigations	Body temperature abnormal	4	4	0
Nervous system disorders	Cerebral venous thrombosis	4	4	1
Reproductive system and breast disorders	Menopausal symptoms	4	4	0
General disorders and administration site conditions	Hangover	4	3	0
Hepatobiliary disorders	Liver disorder	4	4	0
Infections and infestations	Appendicitis perforated	4	4	0
Infections and infestations	Peritonitis	4	4	1
Infections and infestations	Viral rash	4	4	0
Investigations	Urine output decreased	4	3	0
Metabolism and nutrition disorders	Hypokalaemia	4	4	0
Psychiatric disorders	Aggression	4	4	0
Vascular disorders	Phlebitis	4	4	0
Blood and lymphatic system disorders	Haemolysis	3	2	0
Cardiac disorders	Coronary artery thrombosis	3	2	1
General disorders and administration site conditions	Injection site oedema	3	3	0
General disorders and administration site conditions	Loss of control of legs	3	2	0
General disorders and administration site conditions	Sensation of blood flow	3	3	0
Infections and infestations	Peritonsillar abscess	3	3	0
Infections and infestations	Staphylococcal bacteraemia	3	2	1
Injury, poisoning and procedural complications	Underdose	3	3	0
Investigations	Blood lactate dehydrogenase increased	3	2	0
Investigations	Neurological examination normal	3	2	0
Investigations	White blood cell count	3	3	0
Psychiatric disorders	Delusion	3	3	0
Renal and urinary disorders	Nephritis	3	3	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Respiratory, thoracic and mediastinal disorders	Atelectasis	3	3	0
Respiratory, thoracic and mediastinal disorders	Lung opacity	3	3	0
Respiratory, thoracic and mediastinal disorders	Pleural thickening	3	3	0
Skin and subcutaneous tissue disorders	Rosacea	3	3	0
Blood and lymphatic system disorders	Leukopenia	3	3	0
Eye disorders	Retinal tear	3	3	0
Hepatobiliary disorders	Hepatic pain	3	3	0
Infections and infestations	Pneumonia bacterial	3	3	0
Investigations	Eosinophil count increased	3	3	0
Nervous system disorders	Slow speech	3	3	0
Respiratory, thoracic and mediastinal disorders	Pneumothorax	3	2	0
Skin and subcutaneous tissue disorders	Dermatitis acneiform	3	3	0
General disorders and administration site conditions	Adverse reaction	3	3	0
General disorders and administration site conditions	Cyst	3	2	0
General disorders and administration site conditions	Terminal state	3	3	3
Infections and infestations	COVID-19	3	2	0
Infections and infestations	Fungal infection	3	2	0
Injury, poisoning and procedural complications	Scar	3	3	0
Investigations	Pulse absent	3	3	0
Metabolism and nutrition disorders	Hypomagnesaemia	3	3	0
Musculoskeletal and connective tissue disorders	Arthritis reactive	3	2	0
Nervous system disorders	Carotid artery thrombosis	3	3	1
Psychiatric disorders	Tension	3	3	0
Renal and urinary disorders	Renal colic	3	3	0
Reproductive system and breast disorders	Prostatitis	3	3	0
Reproductive system and breast disorders	Vulvovaginal pain	3	3	0
Respiratory, thoracic and mediastinal disorders	Emphysema	3	3	1

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Vascular disorders	Aortic aneurysm	3	3	1
Vascular disorders	Aortic thrombosis	3	3	0
Ear and labyrinth disorders	Deafness bilateral	3	3	0
Gastrointestinal disorders	Irritable bowel syndrome	3	3	0
General disorders and administration site conditions	Scar inflammation	3	3	0
Hepatobiliary disorders	Hepatic lesion	3	3	0
Infections and infestations	Meningitis aseptic	3	3	0
Injury, poisoning and procedural complications	Skin laceration	3	3	0
Investigations	Blood potassium decreased	3	3	0
Investigations	Blood pressure measurement	3	3	0
Investigations	Grip strength decreased	3	3	0
Metabolism and nutrition disorders	Appetite disorder	3	3	0
Metabolism and nutrition disorders	Fluid intake reduced	3	2	1
Respiratory, thoracic and mediastinal disorders	Nasal discharge discolouration	3	1	0
Respiratory, thoracic and mediastinal disorders	Nasal dryness	3	3	0
Surgical and medical procedures	Bed rest	3	3	0
Vascular disorders	Peripheral artery thrombosis	3	3	0
Endocrine disorders	Hypothyroidism	3	3	0
Gastrointestinal disorders	Tongue disorder	3	3	0
General disorders and administration site conditions	Necrosis	3	3	0
Investigations	Temperature difference of extremities	3	3	0
Musculoskeletal and connective tissue disorders	Tendon pain	3	3	0
Nervous system disorders	Myasthenia gravis	3	3	0
Nervous system disorders	Transverse sinus thrombosis	3	1	0
Product issues	Product contamination	3	3	0
Psychiatric disorders	Mental disorder	3	2	0
Cardiac disorders	Cardiac tamponade	3	3	0
Cardiac disorders	Ventricular fibrillation	3	3	0
Eye disorders	Blindness transient	3	3	0
Eye disorders	Eyelid disorder	3	2	0
Gastrointestinal disorders	Anal haemorrhage	3	3	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
General disorders and administration site conditions	Inflammatory pain	3	2	0
Investigations	Blood cholesterol increased	3	3	0
Investigations	Neutrophil count increased	3	3	0
Respiratory, thoracic and mediastinal disorders	Irregular breathing	3	3	0
Skin and subcutaneous tissue disorders	Circumoral swelling	3	3	0
Skin and subcutaneous tissue disorders	Piloerection	3	3	0
Vascular disorders	Arterial occlusive disease	3	3	0
Blood and lymphatic system disorders	Splenic vein thrombosis	3	3	0
Gastrointestinal disorders	Lip pruritus	3	3	0
Gastrointestinal disorders	Oesophagitis	3	3	0
General disorders and administration site conditions	Application site pain	3	3	0
Immune system disorders	Immune system disorder	3	3	0
Infections and infestations	Pyelonephritis	3	3	0
Investigations	Serum ferritin increased	3	3	0
Nervous system disorders	Facial spasm	3	3	0
Psychiatric disorders	Autoscopy	3	3	0
Reproductive system and breast disorders	Endometriosis	3	3	0
Respiratory, thoracic and mediastinal disorders	Orthopnoea	3	3	0
Surgical and medical procedures	Central nervous system stimulation	3	3	0
Surgical and medical procedures	Lymphadenectomy	3	3	0
Vascular disorders	Peripheral circulatory failure	3	3	1
Blood and lymphatic system disorders	Platelet disorder	3	3	0
Gastrointestinal disorders	Mesenteric panniculitis	3	3	0
Gastrointestinal disorders	Rectal tenesmus	3	3	0
General disorders and administration site conditions	Localised oedema	3	3	0
Infections and infestations	Herpes simplex reactivation	3	3	0
Infections and infestations	Vulvovaginal candidiasis	3	3	0
Injury, poisoning and procedural complications	Fracture	3	3	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Injury, poisoning and procedural complications	Medication error	3	2	0
Investigations	Blood thyroid stimulating hormone increased	3	3	0
Nervous system disorders	Petit mal epilepsy	3	3	0
Psychiatric disorders	Tachyphrenia	3	3	0
Respiratory, thoracic and mediastinal disorders	Bronchiectasis	3	3	0
Respiratory, thoracic and mediastinal disorders	Nasal discomfort	3	3	0
Vascular disorders	Capillary leak syndrome	3	3	1
Vascular disorders	Circulatory collapse	3	3	2
Gastrointestinal disorders	Melaena	3	3	0
General disorders and administration site conditions	Injection site induration	3	3	0
Infections and infestations	Pustule	3	3	0
Investigations	Intraocular pressure increased	3	3	0
Nervous system disorders	Cerebral artery thrombosis	3	3	0
Nervous system disorders	Encephalopathy	3	3	1
Nervous system disorders	Thalamic infarction	3	3	0
Psychiatric disorders	Dysphoria	3	2	0
Renal and urinary disorders	Urine odour abnormal	3	2	0
Gastrointestinal disorders	Dental discomfort	3	3	0
Infections and infestations	Herpes virus infection	3	3	0
Infections and infestations	Streptococcal infection	3	3	0
Injury, poisoning and procedural complications	Limb injury	3	3	0
Investigations	Cardiac murmur	3	3	0
Investigations	Lipase increased	3	3	0
Metabolism and nutrition disorders	Acidosis	3	2	1
Metabolism and nutrition disorders	Hyperkalaemia	3	3	1
Musculoskeletal and connective tissue disorders	Joint effusion	3	3	0
Musculoskeletal and connective tissue disorders	Myositis	3	3	0
Nervous system disorders	Clonic convulsion	3	3	0
Nervous system disorders	Multiple sclerosis relapse	3	3	0
Nervous system disorders	Peroneal nerve palsy	3	3	0
Nervous system disorders	Vocal cord paralysis	3	3	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Product issues	Oversensing	3	3	0
Skin and subcutaneous tissue disorders	Palmar erythema	3	3	0
Skin and subcutaneous tissue disorders	Pemphigus	3	3	0
Social circumstances	Impaired work ability	3	3	0
Vascular disorders	Arterial thrombosis	3	3	0
Gastrointestinal disorders	Parotid gland enlargement	3	3	0
Injury, poisoning and procedural complications	Injection related reaction	3	3	0
Investigations	Fibrin D dimer decreased	3	3	0
Reproductive system and breast disorders	Testicular swelling	3	3	0
Skin and subcutaneous tissue disorders	Cold urticaria	3	3	0
Ear and labyrinth disorders	Otorrhoea	3	3	0
Endocrine disorders	Adrenocortical insufficiency acute	3	3	0
Eye disorders	Iritis	3	3	0
Infections and infestations	Bronchiolitis	3	3	0
Musculoskeletal and connective tissue disorders	Psoriatic arthropathy	3	3	0
Musculoskeletal and connective tissue disorders	Weight bearing difficulty	3	3	0
Respiratory, thoracic and mediastinal disorders	Choking sensation	3	3	0
Skin and subcutaneous tissue disorders	Dermatitis bullous	3	3	0
Skin and subcutaneous tissue disorders	Skin lesion	3	3	0
Cardiac disorders	Bundle branch block	2	2	0
Cardiac disorders	Ventricular tachycardia	2	2	0
Gastrointestinal disorders	Mesenteric artery embolism	2	2	1
Gastrointestinal disorders	Tongue erythema	2	2	0
General disorders and administration site conditions	Energy increased	2	2	0
General disorders and administration site conditions	Injection site haematoma	2	2	0
Infections and infestations	Injection site abscess	2	2	0
Infections and infestations	Myelitis	2	2	0
Injury, poisoning and procedural complications	Expired product administered	2	2	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Injury, poisoning and procedural complications	Post procedural haemorrhage	2	2	0
Musculoskeletal and connective tissue disorders	Necrotising myositis	2	2	0
Product issues	Syringe issue	2	2	0
Renal and urinary disorders	Renal disorder	2	2	0
Respiratory, thoracic and mediastinal disorders	Rhonchi	2	2	0
Respiratory, thoracic and mediastinal disorders	Vocal cord disorder	2	2	0
Skin and subcutaneous tissue disorders	Exfoliative rash	2	2	0
Blood and lymphatic system disorders	Polycythaemia	2	2	1
Cardiac disorders	Heart alternation	2	2	0
Eye disorders	Blepharitis	2	2	0
Eye disorders	Blindness unilateral	2	2	1
Eye disorders	Retinal artery thrombosis	2	2	0
Gastrointestinal disorders	Functional gastrointestinal disorder	2	2	0
Gastrointestinal disorders	Small intestinal obstruction	2	2	1
Gastrointestinal disorders	Teething	2	2	0
Gastrointestinal disorders	Tongue discolouration	2	2	0
Gastrointestinal disorders	Tongue haematoma	2	2	0
General disorders and administration site conditions	Impaired healing	2	2	0
Infections and infestations	Periorbital cellulitis	2	2	0
Investigations	Activated partial thromboplastin time prolonged	2	2	0
Investigations	Blood creatine increased	2	2	0
Investigations	Body temperature fluctuation	2	2	0
Investigations	Inflammatory marker increased	2	2	0
Investigations	Platelet count abnormal	2	2	0
Investigations	Sinus rhythm	2	2	0
Investigations	Urine analysis abnormal	2	2	0
Metabolism and nutrition disorders	Feeding disorder	2	2	0
Metabolism and nutrition disorders	Food refusal	2	1	1
Musculoskeletal and connective tissue disorders	Muscle disorder	2	2	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lymphoma	2	2	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	2	2	0
Nervous system disorders	Brain stem infarction	2	2	0
Nervous system disorders	Hemiparaesthesia	2	2	0
Psychiatric disorders	Apathy	2	2	0
Renal and urinary disorders	Renal vein thrombosis	2	2	0
Respiratory, thoracic and mediastinal disorders	Pulmonary haemorrhage	2	2	0
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	2	2	0
Skin and subcutaneous tissue disorders	Butterfly rash	2	2	0
Skin and subcutaneous tissue disorders	Dermatitis atopic	2	2	0
Social circumstances	Immobile	2	2	0
Blood and lymphatic system disorders	Neutrophilia	2	1	0
Cardiac disorders	Angina unstable	2	2	0
Gastrointestinal disorders	Inflammatory bowel disease	2	2	0
General disorders and administration site conditions	Injection site lymphadenopathy	2	2	0
General disorders and administration site conditions	Injection site macule	2	2	0
General disorders and administration site conditions	Serositis	2	2	0
General disorders and administration site conditions	Therapeutic response unexpected	2	2	0
Infections and infestations	Viral upper respiratory tract infection	2	2	0
Investigations	Oxygen saturation	2	2	1
Investigations	Streptococcus test positive	2	1	0
Nervous system disorders	Central nervous system inflammation	2	2	0
Nervous system disorders	Peripheral sensory neuropathy	2	1	0
Nervous system disorders	Radiculitis brachial	2	2	0
Nervous system disorders	Radiculopathy	2	2	0
Nervous system disorders	Trigeminal nerve paresis	2	2	0
Psychiatric disorders	Communication disorder	2	2	0
Psychiatric disorders	Dissociative disorder	2	2	0
Reproductive system and breast disorders	Menstrual discomfort	2	2	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Reproductive system and breast disorders	Pelvic haemorrhage	2	1	0
Respiratory, thoracic and mediastinal disorders	Nasal ulcer	2	2	0
Skin and subcutaneous tissue disorders	Livedo reticularis	2	2	0
Vascular disorders	Peripheral embolism	2	2	0
Eye disorders	Chorioretinopathy	2	2	0
Eye disorders	Exophthalmos	2	2	0
Gastrointestinal disorders	Faeces pale	2	2	0
Hepatobiliary disorders	Liver injury	2	2	0
Infections and infestations	Clostridium difficile infection	2	2	0
Infections and infestations	Pneumonia viral	2	2	1
Injury, poisoning and procedural complications	Incorrect dose administered	2	1	0
Injury, poisoning and procedural complications	Inflammation of wound	2	2	0
Injury, poisoning and procedural complications	Ligament sprain	2	1	0
Injury, poisoning and procedural complications	Oral contusion	2	2	0
Investigations	Blood pressure systolic decreased	2	2	0
Investigations	Computerised tomogram normal	2	2	0
Musculoskeletal and connective tissue disorders	Soft tissue swelling	2	2	0
Nervous system disorders	Cerebral mass effect	2	2	0
Nervous system disorders	Cranial nerve paralysis	2	2	0
Nervous system disorders	Postictal state	2	2	0
Nervous system disorders	Tongue biting	2	2	0
Nervous system disorders	Vertebral artery occlusion	2	2	0
Nervous system disorders	Vestibular migraine	2	2	0
Renal and urinary disorders	Oliguria	2	2	0
Renal and urinary disorders	Urinary tract disorder	2	2	0
Reproductive system and breast disorders	Hypomenorrhoea	2	2	0
Reproductive system and breast disorders	Nipple pain	2	2	0
Skin and subcutaneous tissue disorders	Drug eruption	2	2	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Skin and subcutaneous tissue disorders	Skin haemorrhage	2	2	0
Vascular disorders	Subclavian vein thrombosis	2	2	0
Blood and lymphatic system disorders	Iron deficiency anaemia	2	2	0
Eye disorders	Papilloedema	2	2	0
Eye disorders	Retinal artery embolism	2	2	0
Gastrointestinal disorders	Gastric disorder	2	1	0
Gastrointestinal disorders	Intestinal infarction	2	2	2
General disorders and administration site conditions	Mucosal hypertrophy	2	2	0
Immune system disorders	Bacille Calmette-Guerin scar reactivation	2	2	0
Infections and infestations	Picornavirus infection	2	2	0
Infections and infestations	Respiratory syncytial virus infection	2	2	0
Injury, poisoning and procedural complications	Splenic rupture	2	2	0
Investigations	Ventilation/perfusion scan abnormal	2	2	0
Nervous system disorders	Basal ganglia haemorrhage	2	2	0
Nervous system disorders	Epilepsy	2	2	0
Nervous system disorders	Focal dyscognitive seizures	2	2	0
Nervous system disorders	Hemiplegic migraine	2	2	0
Nervous system disorders	Intracranial aneurysm	2	2	0
Reproductive system and breast disorders	Vulval ulceration	2	2	0
Respiratory, thoracic and mediastinal disorders	Yawning	2	2	0
Vascular disorders	Aortic stenosis	2	2	0
Blood and lymphatic system disorders	Febrile neutropenia	2	1	0
Blood and lymphatic system disorders	Thrombotic thrombocytopenic purpura	2	2	0
Cardiac disorders	Coronary artery embolism	2	2	0
Cardiac disorders	Left ventricular dysfunction	2	2	0
Ear and labyrinth disorders	Ear pruritus	2	2	0
Eye disorders	Pupil fixed	2	2	0
General disorders and administration site conditions	Vaccination site mass	2	2	0
Hepatobiliary disorders	Gallbladder disorder	2	2	0
Hepatobiliary disorders	Hepatic infarction	2	2	1

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Infections and infestations	Epstein-Barr virus infection	2	2	0
Injury, poisoning and procedural complications	Wrist fracture	2	2	0
Injury, poisoning and procedural complications	Wrong technique in product usage process	2	2	0
Investigations	Alanine aminotransferase increased	2	1	0
Musculoskeletal and connective tissue disorders	Arthropathy	2	2	0
Musculoskeletal and connective tissue disorders	Muscle rigidity	2	2	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Haemangioma	2	2	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lung neoplasm malignant	2	2	0
Nervous system disorders	Cerebral ischaemia	2	2	0
Nervous system disorders	Hyposmia	2	2	0
Nervous system disorders	Retinal migraine	2	2	0
Nervous system disorders	Ruptured cerebral aneurysm	2	2	1
Nervous system disorders	Vertebral artery dissection	2	2	0
Psychiatric disorders	Acute stress disorder	2	2	0
Psychiatric disorders	Enuresis	2	2	0
Reproductive system and breast disorders	Penile discharge	2	2	0
Reproductive system and breast disorders	Testicular pain	2	2	0
Respiratory, thoracic and mediastinal disorders	Nasal pruritus	2	1	0
Skin and subcutaneous tissue disorders	Toxic epidermal necrolysis	2	1	0
Vascular disorders	Peripheral vascular disorder	2	2	0
Blood and lymphatic system disorders	Antiphospholipid syndrome	2	2	1
Blood and lymphatic system disorders	Autoimmune haemolytic anaemia	2	2	0
Blood and lymphatic system disorders	Lymphocytosis	2	2	0
Endocrine disorders	Thyroiditis subacute	2	2	0
Eye disorders	Retinal haemorrhage	2	2	0
Gastrointestinal disorders	Chapped lips	2	2	0
Gastrointestinal disorders	Oral contusion	2	2	0
Gastrointestinal disorders	Tongue coated	2	2	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Gastrointestinal disorders	Upper gastrointestinal haemorrhage	2	2	1
Hepatobiliary disorders	Cholecystitis acute	2	2	1
Infections and infestations	Endocarditis	2	2	0
Infections and infestations	Impetigo	2	2	0
Infections and infestations	Meningococcal sepsis	2	2	1
Injury, poisoning and procedural complications	Autonomic dysreflexia	2	2	0
Investigations	Monocyte count increased	2	2	0
Musculoskeletal and connective tissue disorders	Muscle fatigue	2	2	0
Musculoskeletal and connective tissue disorders	Musculoskeletal disorder	2	2	0
Musculoskeletal and connective tissue disorders	Myopathy	2	2	0
Nervous system disorders	Carotid artery occlusion	2	2	0
Nervous system disorders	Sleep deficit	2	2	0
Nervous system disorders	Speech disorder developmental	2	2	0
Renal and urinary disorders	Loss of bladder sensation	2	2	0
Renal and urinary disorders	Proteinuria	2	2	0
Respiratory, thoracic and mediastinal disorders	Lung disorder	2	2	0
Vascular disorders	Venous haemorrhage	2	2	0
Eye disorders	Astigmatism	2	2	0
Gastrointestinal disorders	Coeliac artery aneurysm	2	2	0
Gastrointestinal disorders	Vomiting projectile	2	2	0
General disorders and administration site conditions	Application site reaction	2	2	0
General disorders and administration site conditions	Induration	2	2	0
General disorders and administration site conditions	Symptom recurrence	2	1	0
Infections and infestations	Upper respiratory tract infection bacterial	2	2	0
Investigations	Electrocardiogram QT prolonged	2	2	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pancreatic carcinoma	2	2	0
Nervous system disorders	Acute disseminated encephalomyelitis	2	1	1
Nervous system disorders	Dystonia	2	2	0
Nervous system disorders	Head titubation	2	2	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Nervous system disorders	Reflexes abnormal	2	2	0
Psychiatric disorders	Psychotic disorder	2	2	0
Skin and subcutaneous tissue disorders	Keratosis pilaris	2	2	0
Social circumstances	Walking disability	2	2	0
Surgical and medical procedures	Limb immobilisation	2	2	0
Vascular disorders	Embolism arterial	2	2	1
Vascular disorders	Vena cava thrombosis	2	2	0
Blood and lymphatic system disorders	Microangiopathic haemolytic anaemia	2	2	0
Cardiac disorders	Congestive cardiomyopathy	2	2	1
Eye disorders	Corneal lesion	2	2	0
Eye disorders	Foreign body sensation in eyes	2	2	0
Gastrointestinal disorders	Gingival disorder	2	2	0
General disorders and administration site conditions	Glassy eyes	2	2	0
General disorders and administration site conditions	Injection site scab	2	2	0
Infections and infestations	Adenovirus infection	2	2	0
Infections and infestations	Tooth abscess	2	2	0
Investigations	Blood phosphorus decreased	2	2	0
Investigations	Hepatic enzyme abnormal	2	2	0
Musculoskeletal and connective tissue disorders	Synovitis	2	2	0
Nervous system disorders	Bradykinesia	2	1	0
Nervous system disorders	Cerebellar stroke	2	2	0
Nervous system disorders	Haemorrhagic transformation stroke	2	2	1
Nervous system disorders	Hyporeflexia	2	2	0
Nervous system disorders	Paresis	2	2	0
Psychiatric disorders	Anxiety disorder	2	2	0
Reproductive system and breast disorders	Breast cyst	2	2	0
Reproductive system and breast disorders	Vulvovaginal discomfort	2	2	0
Skin and subcutaneous tissue disorders	Haemorrhage subcutaneous	2	2	0
Skin and subcutaneous tissue disorders	Henoch-Schonlein purpura	2	2	0
Skin and subcutaneous tissue disorders	Urticaria papular	2	2	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Cardiac disorders	Arteriospasm coronary	2	2	0
Cardiac disorders	Coronary artery occlusion	2	2	0
Ear and labyrinth disorders	Middle ear effusion	2	2	0
Gastrointestinal disorders	Cheilitis	2	2	0
Gastrointestinal disorders	Gingival discomfort	2	2	0
Gastrointestinal disorders	Omental infarction	2	2	0
Infections and infestations	Campylobacter infection	2	2	0
Infections and infestations	Croup infectious	2	2	0
Infections and infestations	Escherichia bacteraemia	2	2	0
Injury, poisoning and procedural complications	Accidental underdose	2	2	0
Injury, poisoning and procedural complications	Barotrauma	2	2	0
Injury, poisoning and procedural complications	Vaccination complication	2	2	0
Investigations	Blood pressure diastolic increased	2	2	0
Investigations	QRS axis abnormal	2	2	0
Musculoskeletal and connective tissue disorders	Joint range of motion decreased	2	2	0
Nervous system disorders	Autonomic nervous system imbalance	2	2	0
Nervous system disorders	Brain stem haemorrhage	2	2	1
Nervous system disorders	Dementia	2	2	0
Skin and subcutaneous tissue disorders	Skin odour abnormal	2	2	0
Skin and subcutaneous tissue disorders	Urticaria chronic	2	2	0
Social circumstances	Loss of personal independence in daily activities	2	2	0
Vascular disorders	Peripheral artery occlusion	2	1	0
Blood and lymphatic system disorders	Leukocytosis	2	1	0
Eye disorders	Episcleritis	2	2	0
Eye disorders	Optic neuropathy	2	2	0
Gastrointestinal disorders	Intestinal haemorrhage	2	1	0
Gastrointestinal disorders	Steatorrhoea	2	2	0
General disorders and administration site conditions	Fat necrosis	2	2	0
General disorders and administration site conditions	Hernia	2	2	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
General disorders and administration site conditions	Injection site scar	2	2	0
Hepatobiliary disorders	Hepatic steatosis	2	2	0
Infections and infestations	Bacteraemia	2	1	0
Infections and infestations	Epstein-Barr virus infection reactivation	2	1	0
Infections and infestations	Hordeolum	2	2	0
Injury, poisoning and procedural complications	Exposure during pregnancy	2	2	0
Injury, poisoning and procedural complications	Tendon rupture	2	2	0
Injury, poisoning and procedural complications	Wound	2	2	0
Investigations	Glomerular filtration rate decreased	2	2	0
Musculoskeletal and connective tissue disorders	Joint noise	2	2	0
Musculoskeletal and connective tissue disorders	Sacroiliitis	2	2	0
Nervous system disorders	Diplegia	2	2	0
Reproductive system and breast disorders	Uterine polyp	2	2	0
Skin and subcutaneous tissue disorders	Pigmentation disorder	2	2	0
Vascular disorders	Embolism venous	2	2	0
Vascular disorders	Labile blood pressure	2	2	0
Ear and labyrinth disorders	Vertigo labyrinthine	2	2	0
Eye disorders	Acute macular outer retinopathy	2	1	0
Gastrointestinal disorders	Inguinal hernia	2	2	0
Gastrointestinal disorders	Mesenteric artery thrombosis	2	2	1
General disorders and administration site conditions	Systemic inflammatory response syndrome	2	2	0
Infections and infestations	Eye infection bacterial	2	2	0
Investigations	Blood bilirubin increased	2	2	0
Investigations	Blood potassium abnormal	2	2	0
Metabolism and nutrition disorders	Diabetes mellitus inadequate control	2	2	0
Musculoskeletal and connective tissue disorders	Myokymia	2	2	0
Nervous system disorders	Brain stem stroke	2	2	0
Nervous system disorders	Polyneuropathy	2	1	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Nervous system disorders	Vertebrobasilar insufficiency	2	2	0
Psychiatric disorders	Catatonia	2	2	0
Psychiatric disorders	Conversion disorder	2	2	0
Psychiatric disorders	Libido decreased	2	2	0
Psychiatric disorders	Tearfulness	2	2	0
Reproductive system and breast disorders	Vaginal discharge	2	2	0
Respiratory, thoracic and mediastinal disorders	Bronchial wall thickening	2	2	0
Respiratory, thoracic and mediastinal disorders	Laryngospasm	2	2	0
Vascular disorders	Subclavian artery thrombosis	2	2	0
Blood and lymphatic system disorders	Increased tendency to bruise	1	1	0
Blood and lymphatic system disorders	Normocytic anaemia	1	1	0
Cardiac disorders	Atrioventricular block complete	1	1	0
Cardiac disorders	Cardiac fibrillation	1	1	0
Cardiac disorders	Cardio-respiratory distress	1	1	0
Cardiac disorders	Pericardial fibrosis	1	1	0
Ear and labyrinth disorders	Auricular swelling	1	1	0
Endocrine disorders	Hyperaldosteronism	1	1	0
Eye disorders	Holmes-Adie pupil	1	1	0
Eye disorders	Ulcerative keratitis	1	1	0
Gastrointestinal disorders	Abdominal hernia	1	1	0
Gastrointestinal disorders	Ascites	1	1	0
Gastrointestinal disorders	Gastric varices haemorrhage	1	1	0
Gastrointestinal disorders	Haemoperitoneum	1	1	0
Gastrointestinal disorders	Intestinal perforation	1	1	0
Gastrointestinal disorders	Lip oedema	1	1	0
Gastrointestinal disorders	Tongue haemorrhage	1	0	0
General disorders and administration site conditions	Injection site dermatitis	1	1	0
General disorders and administration site conditions	Injection site irritation	1	1	0
General disorders and administration site conditions	Injection site joint movement impairment	1	1	0
General disorders and administration site conditions	Injection site necrosis	1	1	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
General disorders and administration site conditions	Unevaluable event	1	1	0
Hepatobiliary disorders	Autoimmune hepatitis	1	1	0
Hepatobiliary disorders	Hepatomegaly	1	0	0
Infections and infestations	Arthritis bacterial	1	1	0
Infections and infestations	Arthritis infective	1	1	0
Infections and infestations	Asymptomatic COVID-19	1	1	0
Infections and infestations	Erythema induratum	1	1	0
Infections and infestations	Infectious mononucleosis	1	1	0
Infections and infestations	Muscle abscess	1	1	0
Infections and infestations	Viral pericarditis	1	1	0
Injury, poisoning and procedural complications	Foreign body in eye	1	1	0
Injury, poisoning and procedural complications	Incorrect dosage administered	1	1	0
Injury, poisoning and procedural complications	Incorrect product administration duration	1	1	0
Injury, poisoning and procedural complications	Joint injury	1	1	0
Injury, poisoning and procedural complications	Lip injury	1	1	0
Injury, poisoning and procedural complications	Lower limb fracture	1	1	0
Injury, poisoning and procedural complications	Product dispensing error	1	1	0
Injury, poisoning and procedural complications	Wrong product administered	1	1	0
Investigations	Base excess	1	1	0
Investigations	Biopsy artery	1	1	0
Investigations	Blood urea abnormal	1	1	0
Investigations	Breath sounds	1	1	0
Investigations	Epinephrine abnormal	1	1	0
Investigations	Gamma-glutamyltransferase increased	1	1	0
Investigations	Glomerular filtration rate	1	1	0
Investigations	Human rhinovirus test positive	1	1	0
Investigations	Investigation	1	1	0
Investigations	Lumbar puncture	1	1	0
Investigations	Lymphocyte count decreased	1	1	0
Investigations	Renal function test abnormal	1	1	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Investigations	Serum ferritin decreased	1	1	0
Investigations	Ultrasound joint	1	1	0
Musculoskeletal and connective tissue disorders	Polymyositis	1	1	0
Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	1	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Testis cancer	1	1	0
Nervous system disorders	Cytotoxic oedema	1	1	0
Nervous system disorders	IVth nerve paralysis	1	1	0
Nervous system disorders	Migraine without aura	1	1	0
Nervous system disorders	Myelopathy	1	1	0
Nervous system disorders	Quadriplegia	1	0	0
Nervous system disorders	Reversible cerebral vasoconstriction syndrome	1	1	0
Nervous system disorders	Sleep paralysis	1	1	0
Nervous system disorders	Spinal artery thrombosis	1	1	0
Nervous system disorders	Spinal cord infarction	1	1	0
Nervous system disorders	Typical aura without headache	1	1	0
Pregnancy, puerperium and perinatal conditions	Foetal death	1	1	0
Pregnancy, puerperium and perinatal conditions	Morning sickness	1	1	0
Psychiatric disorders	Frustration tolerance decreased	1	1	0
Psychiatric disorders	Impatience	1	1	0
Psychiatric disorders	Loss of libido	1	1	0
Psychiatric disorders	Self-injurious ideation	1	1	0
Reproductive system and breast disorders	Genital rash	1	1	0
Reproductive system and breast disorders	Uterine haemorrhage	1	1	0
Respiratory, thoracic and mediastinal disorders	Hypersensitivity pneumonitis	1	1	0
Respiratory, thoracic and mediastinal disorders	Laryngeal oedema	1	1	0
Respiratory, thoracic and mediastinal disorders	Painful respiration	1	1	0
Respiratory, thoracic and mediastinal disorders	Respiratory tract congestion	1	1	0
Skin and subcutaneous tissue disorders	Capillaritis	1	1	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Skin and subcutaneous tissue disorders	Scab	1	1	0
Skin and subcutaneous tissue disorders	Stevens-Johnson syndrome	1	1	0
Skin and subcutaneous tissue disorders	Telangiectasia	1	1	0
Social circumstances	Sitting disability	1	1	0
Surgical and medical procedures	Analgesic therapy	1	1	0
Surgical and medical procedures	Injectable contraception	1	1	0
Vascular disorders	Superficial vein prominence	1	1	0
Blood and lymphatic system disorders	Bicytopenia	1	0	0
Blood and lymphatic system disorders	Eosinophilia	1	1	0
Cardiac disorders	Supraventricular tachyarrhythmia	1	1	0
Congenital, familial and genetic disorders	Gastrointestinal malformation	1	1	0
Congenital, familial and genetic disorders	Thyroglossal cyst	1	1	0
Endocrine disorders	Adrenal insufficiency	1	1	0
Endocrine disorders	Adrenal mass	1	1	0
Eye disorders	Miosis	1	1	0
Gastrointestinal disorders	Crohn's disease	1	1	0
Gastrointestinal disorders	Diverticulum	1	1	0
Gastrointestinal disorders	Faeces soft	1	1	0
Gastrointestinal disorders	Gastrointestinal oedema	1	1	0
Gastrointestinal disorders	Ileus paralytic	1	1	0
Gastrointestinal disorders	Oral discharge	1	1	0
Gastrointestinal disorders	Salivary gland pain	1	1	0
General disorders and administration site conditions	Drug intolerance	1	1	0
General disorders and administration site conditions	Injection site joint swelling	1	1	0
Infections and infestations	Abdominal infection	1	1	0
Infections and infestations	Blister infected	1	1	0
Infections and infestations	Lymph gland infection	1	1	0
Infections and infestations	Malassezia infection	1	1	0
Infections and infestations	Pertussis	1	1	0
Infections and infestations	Staphylococcal sepsis	1	1	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Infections and infestations	Wound abscess	1	1	0
Injury, poisoning and procedural complications	Drug monitoring procedure incorrectly performed	1	1	0
Injury, poisoning and procedural complications	Extra dose administered	1	1	0
Injury, poisoning and procedural complications	Foot fracture	1	1	0
Injury, poisoning and procedural complications	Off label use	1	0	0
Injury, poisoning and procedural complications	Product use issue	1	1	0
Injury, poisoning and procedural complications	Vascular pseudoaneurysm	1	1	0
Injury, poisoning and procedural complications	Wound secretion	1	1	0
Investigations	Amylase increased	1	1	0
Investigations	Blood potassium increased	1	1	0
Investigations	Blood pressure immeasurable	1	1	0
Investigations	Blood urea decreased	1	1	0
Investigations	Carotid pulse increased	1	1	0
Investigations	Electrocardiogram normal	1	1	0
Investigations	Haptoglobin decreased	1	1	0
Investigations	PCO2 abnormal	1	1	0
Investigations	Quality of life decreased	1	0	0
Investigations	Respiratory syncytial virus test	1	1	0
Investigations	Vitamin B12 decreased	1	1	0
Musculoskeletal and connective tissue disorders	Compartment syndrome	1	1	0
Musculoskeletal and connective tissue disorders	Nuchal rigidity	1	1	0
Musculoskeletal and connective tissue disorders	Osteitis	1	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Gastrointestinal carcinoma	1	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal cell carcinoma	1	1	0
Nervous system disorders	Cold-stimulus headache	1	1	0
Nervous system disorders	Embolic cerebellar infarction	1	1	0
Nervous system disorders	Neurologic neglect syndrome	1	1	0
Nervous system disorders	Orthostatic tremor	1	1	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Psychiatric disorders	Depression suicidal	1	1	0
Psychiatric disorders	Sleep disorder due to general medical condition, insomnia type	1	1	0
Renal and urinary disorders	Bladder pain	1	1	0
Renal and urinary disorders	Reflux nephropathy	1	1	0
Reproductive system and breast disorders	Genital ulceration	1	1	0
Reproductive system and breast disorders	Menopausal disorder	1	1	0
Reproductive system and breast disorders	Painful erection	1	1	0
Reproductive system and breast disorders	Scrotal oedema	1	1	0
Reproductive system and breast disorders	Uterine pain	1	1	0
Reproductive system and breast disorders	Vaginal haematoma	1	1	0
Respiratory, thoracic and mediastinal disorders	Bronchitis chronic	1	1	0
Respiratory, thoracic and mediastinal disorders	Cyanosis central	1	1	0
Respiratory, thoracic and mediastinal disorders	Respiratory tract inflammation	1	1	0
Respiratory, thoracic and mediastinal disorders	Ventilation perfusion mismatch	1	1	0
Skin and subcutaneous tissue disorders	Alopecia areata	1	1	0
Surgical and medical procedures	Anaphylaxis treatment	1	1	0
Surgical and medical procedures	Cholecystectomy	1	1	0
Surgical and medical procedures	Eye irrigation	1	1	0
Surgical and medical procedures	Spinal decompression	1	1	0
Vascular disorders	Accelerated hypertension	1	1	0
Vascular disorders	Bloody discharge	1	1	0
Vascular disorders	Microangiopathy	1	1	0
Vascular disorders	Pelvic venous thrombosis	1	1	0
Vascular disorders	Vasoconstriction	1	1	0
Blood and lymphatic system disorders	Agranulocytosis	1	1	0
Blood and lymphatic system disorders	Haemolytic anaemia	1	1	0
Blood and lymphatic system disorders	Hypercoagulation	1	1	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Cardiac disorders	Aortic valve incompetence	1	1	0
Cardiac disorders	Left ventricular dilatation	1	1	0
Cardiac disorders	Right ventricular dysfunction	1	1	0
Cardiac disorders	Sinus arrest	1	1	0
Congenital, familial and genetic disorders	Intracranial lipoma	1	1	0
Ear and labyrinth disorders	Excessive cerumen production	1	1	0
Eye disorders	Conjunctivitis allergic	1	1	0
Eye disorders	Heterophoria	1	1	0
Eye disorders	Optic nerve disorder	1	1	0
Eye disorders	Retinopathy	1	1	0
Gastrointestinal disorders	Intra-abdominal haematoma	1	1	0
Gastrointestinal disorders	Mucous stools	1	1	0
Gastrointestinal disorders	Oral disorder	1	1	0
Gastrointestinal disorders	Retroperitoneal haematoma	1	1	0
Gastrointestinal disorders	Tongue dry	1	1	0
Gastrointestinal disorders	Tongue rough	1	1	0
General disorders and administration site conditions	Device related thrombosis	1	1	0
General disorders and administration site conditions	Foaming at mouth	1	1	0
General disorders and administration site conditions	Injection site extravasation	1	1	0
General disorders and administration site conditions	Organ failure	1	0	0
General disorders and administration site conditions	Strangulated hernia	1	1	0
General disorders and administration site conditions	Vaccination site joint inflammation	1	1	0
Hepatobiliary disorders	Cholangitis	1	1	0
Hepatobiliary disorders	Congestive hepatopathy	1	1	0
Immune system disorders	Allergy to arthropod sting	1	1	0
Immune system disorders	Anti-neutrophil cytoplasmic antibody positive vasculitis	1	1	0
Infections and infestations	Erysipelas	1	1	0
Infections and infestations	Gastroenteritis viral	1	1	0
Infections and infestations	Large intestine infection	1	1	0
Infections and infestations	Nasal vestibulitis	1	1	0
Infections and infestations	Oesophageal candidiasis	1	1	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Injury, poisoning and procedural complications	Scratch	1	0	0
Injury, poisoning and procedural complications	Wound complication	1	1	0
Investigations	Antipsychotic drug level increased	1	0	0
Investigations	Bilirubin conjugated increased	1	1	0
Investigations	Blood immunoglobulin E increased	1	1	0
Investigations	Blood sodium decreased	1	1	0
Investigations	Carbon dioxide abnormal	1	1	0
Investigations	Coagulation test abnormal	1	1	0
Investigations	Electrocardiogram ST-T segment abnormal	1	1	0
Investigations	Enterococcus test positive	1	1	0
Investigations	Granulocyte-colony stimulating factor level increased	1	1	0
Investigations	Norovirus test positive	1	1	0
Investigations	Platelet count normal	1	1	0
Investigations	Popliteal pulse	1	1	0
Investigations	Rheumatoid factor increased	1	1	0
Metabolism and nutrition disorders	Hyperchloraemia	1	1	0
Musculoskeletal and connective tissue disorders	Autoimmune arthritis	1	0	0
Musculoskeletal and connective tissue disorders	Decreased nasolabial fold	1	1	0
Musculoskeletal and connective tissue disorders	Haemarthrosis	1	1	0
Musculoskeletal and connective tissue disorders	Haematoma muscle	1	1	0
Musculoskeletal and connective tissue disorders	Osteonecrosis	1	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Plasma cell myeloma	1	1	0
Nervous system disorders	Athetosis	1	1	0
Nervous system disorders	Ballismus	1	1	0
Nervous system disorders	Cerebellar artery thrombosis	1	1	0
Nervous system disorders	Meningism	1	1	0
Nervous system disorders	Optic perineuritis	1	1	0
Nervous system disorders	Status epilepticus	1	1	0
Psychiatric disorders	Indifference	1	1	0
Psychiatric disorders	Mutism	1	1	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Psychiatric disorders	Sleep attacks	1	1	0
Renal and urinary disorders	Renal injury	1	1	0
Reproductive system and breast disorders	Haematospermia	1	1	0
Reproductive system and breast disorders	Uterine spasm	1	1	0
Reproductive system and breast disorders	Vulvovaginal swelling	1	1	0
Respiratory, thoracic and mediastinal disorders	Hypercapnia	1	1	0
Respiratory, thoracic and mediastinal disorders	Pneumothorax spontaneous	1	1	0
Respiratory, thoracic and mediastinal disorders	Respiratory tract irritation	1	1	0
Respiratory, thoracic and mediastinal disorders	Tonsillolith	1	1	0
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	1	1	0
Skin and subcutaneous tissue disorders	Leukoplakia	1	1	0
Skin and subcutaneous tissue disorders	Macule	1	1	0
Skin and subcutaneous tissue disorders	Pruritus allergic	1	1	0
Skin and subcutaneous tissue disorders	Skin oedema	1	1	0
Vascular disorders	Malignant hypertension	1	1	0
Blood and lymphatic system disorders	Thrombocytopenic purpura	1	1	0
Ear and labyrinth disorders	Acute vestibular syndrome	1	1	0
Eye disorders	Conjunctival hyperaemia	1	1	0
Eye disorders	Dyschromatopsia	1	1	0
Eye disorders	Eye allergy	1	1	0
Gastrointestinal disorders	Abdominal migraine	1	1	0
Gastrointestinal disorders	Faecal vomiting	1	1	1
Gastrointestinal disorders	Gastrointestinal inflammation	1	1	0
Gastrointestinal disorders	Gastrointestinal perforation	1	1	0
Gastrointestinal disorders	Volvulus	1	1	0
General disorders and administration site conditions	Injection site joint pain	1	1	0
General disorders and administration site conditions	Sudden death	1	1	1

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
General disorders and administration site conditions	Vaccination site erythema	1	1	0
Immune system disorders	Haemophagocytic lymphohistiocytosis	1	1	0
Infections and infestations	Coxsackie viral infection	1	1	0
Infections and infestations	Endocarditis bacterial	1	1	0
Infections and infestations	Enterococcal infection	1	1	0
Infections and infestations	Molluscum contagiosum	1	1	0
Infections and infestations	Prostate infection	1	1	0
Infections and infestations	Respiratory syncytial virus bronchitis	1	0	0
Infections and infestations	Systemic candida	1	1	1
Infections and infestations	Vulvovaginal mycotic infection	1	1	0
Injury, poisoning and procedural complications	Facial bones fracture	1	1	0
Injury, poisoning and procedural complications	Head injury	1	1	0
Injury, poisoning and procedural complications	Immunisation anxiety related reaction	1	1	0
Injury, poisoning and procedural complications	Muscle injury	1	1	0
Investigations	Blood insulin	1	1	0
Investigations	Blood pressure ambulatory decreased	1	1	0
Investigations	Blood pressure diastolic decreased	1	1	0
Investigations	Cytomegalovirus test positive	1	1	0
Investigations	Electrocardiogram repolarisation abnormality	1	1	0
Investigations	Neutrophil count	1	1	0
Investigations	Neutrophil count abnormal	1	1	0
Investigations	Respiratory syncytial virus test positive	1	1	0
Investigations	Transaminases increased	1	1	0
Metabolism and nutrition disorders	Cachexia	1	1	0
Metabolism and nutrition disorders	Hypocalcaemia	1	1	0
Musculoskeletal and connective tissue disorders	Mandibular mass	1	1	0
Musculoskeletal and connective tissue disorders	Oligoarthritis	1	1	0
Musculoskeletal and connective tissue disorders	Patellofemoral pain syndrome	1	1	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Musculoskeletal and connective tissue disorders	Plantar fasciitis	1	1	0
Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	1	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Neuroma	1	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin papilloma	1	1	0
Nervous system disorders	Cauda equina syndrome	1	1	0
Nervous system disorders	Cerebellar infarction	1	1	0
Nervous system disorders	Clonus	1	1	0
Nervous system disorders	Coma	1	1	0
Nervous system disorders	Glossopharyngeal neuralgia	1	1	0
Nervous system disorders	Neurological decompensation	1	1	0
Pregnancy, puerperium and perinatal conditions	Foetal growth restriction	1	1	0
Psychiatric disorders	Abnormal sleep-related event	1	0	0
Psychiatric disorders	Hypervigilance	1	1	0
Psychiatric disorders	Hypnagogic hallucination	1	1	0
Psychiatric disorders	Hypnopompic hallucination	1	1	0
Psychiatric disorders	Mania	1	1	0
Psychiatric disorders	Sleep talking	1	1	0
Psychiatric disorders	Trance	1	1	0
Renal and urinary disorders	Renal artery thrombosis	1	1	0
Reproductive system and breast disorders	Penile oedema	1	1	0
Reproductive system and breast disorders	Vulval disorder	1	1	0
Respiratory, thoracic and mediastinal disorders	Lung consolidation	1	1	0
Respiratory, thoracic and mediastinal disorders	Pharyngeal haemorrhage	1	1	0
Skin and subcutaneous tissue disorders	Anhidrosis	1	1	0
Skin and subcutaneous tissue disorders	Dermal cyst	1	1	0
Skin and subcutaneous tissue disorders	Diabetic ulcer	1	1	0
Skin and subcutaneous tissue disorders	Erythema nodosum	1	1	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Skin and subcutaneous tissue disorders	Nail bed tenderness	1	1	0
Skin and subcutaneous tissue disorders	Perioral dermatitis	1	1	0
Surgical and medical procedures	COVID-19 immunisation	1	0	0
Blood and lymphatic system disorders	Myeloid maturation arrest	1	1	0
Cardiac disorders	Supraventricular extrasystoles	1	1	0
Cardiac disorders	Tachycardia paroxysmal	1	1	0
Eye disorders	Amaurosis fugax	1	1	0
Eye disorders	Angle closure glaucoma	1	1	0
Eye disorders	Conjunctival cyst	1	1	0
Eye disorders	Iridocyclitis	1	0	0
Eye disorders	Optic ischaemic neuropathy	1	1	0
Eye disorders	Strabismus	1	1	0
Gastrointestinal disorders	Enlarged uvula	1	1	0
Gastrointestinal disorders	Hypertrophy of tongue papillae	1	1	0
Gastrointestinal disorders	Lip discolouration	1	1	0
Gastrointestinal disorders	Salivary gland enlargement	1	1	0
General disorders and administration site conditions	Injection site abscess sterile	1	1	0
General disorders and administration site conditions	Injection site joint warmth	1	1	0
General disorders and administration site conditions	Papillitis	1	1	0
Immune system disorders	Decreased immune responsiveness	1	0	0
Infections and infestations	Hand-foot-and-mouth disease	1	1	0
Injury, poisoning and procedural complications	Fibula fracture	1	1	0
Injury, poisoning and procedural complications	Maternal exposure during breast feeding	1	1	0
Injury, poisoning and procedural complications	Seroma	1	1	0
Injury, poisoning and procedural complications	Stoma site haemorrhage	1	1	0
Investigations	Anion gap abnormal	1	1	0
Investigations	Bleeding time abnormal	1	1	0
Investigations	Blood creatine abnormal	1	1	0
Investigations	Brain natriuretic peptide increased	1	1	0
Investigations	SARS-CoV-2 test positive	1	1	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Investigations	Troponin	1	1	0
Metabolism and nutrition disorders	Food intolerance	1	1	0
Metabolism and nutrition disorders	Glucose tolerance impaired	1	1	0
Metabolism and nutrition disorders	Hypovitaminosis	1	1	0
Metabolism and nutrition disorders	Poor feeding infant	1	1	0
Metabolism and nutrition disorders	Tetany	1	1	0
Musculoskeletal and connective tissue disorders	Coccydynia	1	1	0
Musculoskeletal and connective tissue disorders	Muscle swelling	1	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Histiocytic necrotising lymphadenitis	1	1	0
Nervous system disorders	Basilar artery occlusion	1	1	0
Nervous system disorders	Brain injury	1	0	0
Nervous system disorders	Choreoathetosis	1	1	0
Nervous system disorders	Consciousness fluctuating	1	1	0
Nervous system disorders	Haemorrhagic cerebral infarction	1	1	0
Nervous system disorders	Horner's syndrome	1	1	0
Nervous system disorders	Illrd nerve paralysis	1	1	0
Nervous system disorders	Irregular sleep phase	1	1	0
Nervous system disorders	White matter lesion	1	1	0
Product issues	Device issue	1	1	0
Product issues	Device occlusion	1	1	0
Psychiatric disorders	Feeling of despair	1	1	0
Renal and urinary disorders	Renal ischaemia	1	1	1
Reproductive system and breast disorders	Perineal pain	1	1	0
Respiratory, thoracic and mediastinal disorders	Dyspnoea at rest	1	1	0
Respiratory, thoracic and mediastinal disorders	Paranasal sinus hyposecretion	1	1	0
Skin and subcutaneous tissue disorders	Cutaneous lupus erythematosus	1	1	0
Skin and subcutaneous tissue disorders	Yellow skin	1	1	0
Surgical and medical procedures	Antibiotic therapy	1	1	0
Surgical and medical procedures	Trendelenburg position	1	1	0
Vascular disorders	Arteriosclerosis	1	1	0
Vascular disorders	Artery dissection	1	1	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Vascular disorders	Brachiocephalic vein thrombosis	1	1	0
Blood and lymphatic system disorders	Splenic artery thrombosis	1	1	0
Cardiac disorders	Atrioventricular block first degree	1	1	0
Cardiac disorders	Cardiac aneurysm	1	1	0
Cardiac disorders	Hypertensive heart disease	1	1	1
Ear and labyrinth disorders	Inner ear inflammation	1	1	0
Eye disorders	Endocrine ophthalmopathy	1	1	0
Eye disorders	Gaze palsy	1	1	0
Eye disorders	Keratoconus	1	1	0
Eye disorders	Retinal exudates	1	1	0
Eye disorders	Vitreous haemorrhage	1	1	0
Gastrointestinal disorders	Erosive oesophagitis	1	1	1
Gastrointestinal disorders	Gastric dilatation	1	1	0
Gastrointestinal disorders	Gastrointestinal ulcer	1	1	0
Gastrointestinal disorders	Impaired gastric emptying	1	1	0
Gastrointestinal disorders	Intussusception	1	1	0
General disorders and administration site conditions	Hyperthermia	1	1	0
General disorders and administration site conditions	Injection site cyst	1	1	0
Hepatobiliary disorders	Hepatic cirrhosis	1	1	0
Infections and infestations	Dysentery	1	1	0
Infections and infestations	Lymphangitis	1	1	0
Infections and infestations	Pharyngitis streptococcal	1	1	0
Infections and infestations	Pneumonia pneumococcal	1	1	0
Infections and infestations	Pneumonia staphylococcal	1	1	0
Infections and infestations	Viral sinusitis	1	1	0
Injury, poisoning and procedural complications	Concussion	1	1	0
Investigations	Activated partial thromboplastin time shortened	1	1	0
Investigations	Blood magnesium decreased	1	1	0
Investigations	Chest X-ray normal	1	1	0
Investigations	Enterovirus test positive	1	1	0
Investigations	Eosinophil count	1	1	0
Investigations	Gastrointestinal stoma output decreased	1	0	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Investigations	Interferon gamma release assay positive	1	1	0
Investigations	Red blood cell count decreased	1	1	0
Musculoskeletal and connective tissue disorders	Torticollis	1	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal neoplasm	1	1	0
Nervous system disorders	Dysdiadochokinesis	1	1	0
Nervous system disorders	Encephalitis post immunisation	1	1	0
Nervous system disorders	Hemianopia homonymous	1	1	0
Nervous system disorders	Intraventricular haemorrhage	1	1	1
Nervous system disorders	Muscle tension dysphonia	1	1	0
Nervous system disorders	Phantom limb syndrome	1	1	0
Nervous system disorders	Spinal cord ischaemia	1	1	0
Pregnancy, puerperium and perinatal conditions	Shoulder dystocia	1	1	0
Pregnancy, puerperium and perinatal conditions	Uterine contractions abnormal	1	1	0
Psychiatric disorders	Immunisation anxiety related reaction	1	1	0
Psychiatric disorders	Phonophobia	1	1	0
Renal and urinary disorders	Lower urinary tract symptoms	1	1	0
Reproductive system and breast disorders	Gynaecomastia	1	1	0
Reproductive system and breast disorders	Priapism	1	1	0
Respiratory, thoracic and mediastinal disorders	Allergic respiratory disease	1	1	0
Respiratory, thoracic and mediastinal disorders	Catarrh	1	1	0
Skin and subcutaneous tissue disorders	Blister rupture	1	1	0
Skin and subcutaneous tissue disorders	Dandruff	1	1	0
Skin and subcutaneous tissue disorders	Hair colour changes	1	1	0
Skin and subcutaneous tissue disorders	Mucocutaneous haemorrhage	1	1	0
Skin and subcutaneous tissue disorders	Nail bed inflammation	1	1	0
Skin and subcutaneous tissue disorders	Nikolsky's sign	1	1	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Skin and subcutaneous tissue disorders	Skin weeping	1	1	0
Surgical and medical procedures	Oxygen therapy	1	1	0
Vascular disorders	Intermittent claudication	1	1	0
Cardiac disorders	Coronary artery dissection	1	1	0
Ear and labyrinth disorders	Ear canal erythema	1	1	0
Ear and labyrinth disorders	Meniere's disease	1	1	0
Gastrointestinal disorders	Haemorrhoidal haemorrhage	1	1	0
Gastrointestinal disorders	Lip disorder	1	1	0
Gastrointestinal disorders	Oesophageal spasm	1	1	0
Gastrointestinal disorders	Uvulitis	1	1	0
General disorders and administration site conditions	Effusion	1	1	0
Hepatobiliary disorders	Gallbladder mass	1	1	1
Infections and infestations	Bacterial diarrhoea	1	1	0
Infections and infestations	Cellulitis orbital	1	1	0
Infections and infestations	Dientamoeba infection	1	1	0
Infections and infestations	Escherichia infection	1	1	0
Injury, poisoning and procedural complications	Hyphaema	1	1	0
Injury, poisoning and procedural complications	Tongue injury	1	1	0
Investigations	Blood bicarbonate abnormal	1	1	0
Investigations	Blood creatinine increased	1	1	0
Investigations	Blood ketone body increased	1	1	0
Investigations	Blood lactic acid abnormal	1	1	0
Investigations	Blood pressure ambulatory normal	1	1	0
Investigations	Coma scale normal	1	1	0
Investigations	Computerised tomogram	1	1	0
Investigations	Electrocardiogram	1	1	0
Investigations	Myocardial necrosis marker increased	1	0	0
Metabolism and nutrition disorders	Hypercalcaemia	1	1	0
Musculoskeletal and connective tissue disorders	Spondylitis	1	1	0
Musculoskeletal and connective tissue disorders	Tendon discomfort	1	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Endometrial cancer	1	1	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Nervous system disorders	Akathisia	1	1	0
Nervous system disorders	Arachnoid cyst	1	1	0
Nervous system disorders	Areflexia	1	1	0
Nervous system disorders	Idiopathic intracranial hypertension	1	1	0
Nervous system disorders	Posterior reversible encephalopathy syndrome	1	1	0
Pregnancy, puerperium and perinatal conditions	Gestational hypertension	1	1	0
Psychiatric disorders	Bruxism	1	1	0
Psychiatric disorders	Disturbance in sexual arousal	1	1	0
Psychiatric disorders	Hallucination, tactile	1	1	0
Renal and urinary disorders	Cystitis haemorrhagic	1	1	0
Renal and urinary disorders	Neurogenic bladder	1	1	0
Renal and urinary disorders	Urethral haemorrhage	1	1	0
Renal and urinary disorders	Urinary hesitation	1	1	0
Reproductive system and breast disorders	Ovarian cyst ruptured	1	1	0
Reproductive system and breast disorders	Premenstrual pain	1	1	0
Reproductive system and breast disorders	Scrotal swelling	1	1	0
Reproductive system and breast disorders	Vulvovaginal pruritus	1	1	0
Respiratory, thoracic and mediastinal disorders	Increased upper airway secretion	1	1	0
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	1	1	0
Respiratory, thoracic and mediastinal disorders	Paranasal sinus inflammation	1	1	0
Respiratory, thoracic and mediastinal disorders	Rhinalgia	1	1	0
Skin and subcutaneous tissue disorders	Chronic spontaneous urticaria	1	0	0
Skin and subcutaneous tissue disorders	Nail disorder	1	1	0
Skin and subcutaneous tissue disorders	Papule	1	1	0
Skin and subcutaneous tissue disorders	Pustular psoriasis	1	1	0
Surgical and medical procedures	Menstrual cycle management	1	1	0
Vascular disorders	Aortic dilatation	1	1	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Blood and lymphatic system disorders	Haemorrhagic diathesis	1	1	0
Cardiac disorders	Cardiac perfusion defect	1	1	0
Cardiac disorders	Coronary ostial stenosis	1	1	0
Cardiac disorders	Left ventricular failure	1	1	0
Cardiac disorders	Myocardial fibrosis	1	1	0
Cardiac disorders	Stress cardiomyopathy	1	1	0
Cardiac disorders	Tachyarrhythmia	1	1	0
Cardiac disorders	Tricuspid valve incompetence	1	1	0
Congenital, familial and genetic disorders	Factor VIII deficiency	1	1	0
Eye disorders	Extraocular muscle paresis	1	1	0
Eye disorders	Ocular rosacea	1	1	0
Eye disorders	Panophthalmitis	1	1	0
Gastrointestinal disorders	Mesenteric haemorrhage	1	1	0
Gastrointestinal disorders	Tongue oedema	1	1	0
General disorders and administration site conditions	Administration site bruise	1	1	0
General disorders and administration site conditions	Discharge	1	1	0
General disorders and administration site conditions	Disease recurrence	1	1	0
General disorders and administration site conditions	Drug interaction	1	1	0
General disorders and administration site conditions	Injection site indentation	1	1	0
General disorders and administration site conditions	Mucosal ulceration	1	1	0
General disorders and administration site conditions	Therapeutic product effect decreased	1	0	0
Hepatobiliary disorders	Hyperbilirubinaemia	1	1	0
Immune system disorders	Sensitisation	1	1	0
Infections and infestations	Abdominal sepsis	1	1	0
Infections and infestations	Herpes ophthalmic	1	1	0
Infections and infestations	Injection site pustule	1	1	0
Injury, poisoning and procedural complications	Nasal injury	1	1	0
Injury, poisoning and procedural complications	Parasympathetic nerve injury	1	1	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Injury, poisoning and procedural complications	Vulvovaginal injury	1	1	0
Investigations	Angiogram	1	1	0
Investigations	Aspartate aminotransferase increased	1	1	0
Investigations	Blood iron abnormal	1	1	0
Investigations	Blood test	1	1	0
Investigations	Lymphocyte morphology abnormal	1	1	0
Investigations	Pregnancy test negative	1	0	0
Investigations	Sputum abnormal	1	1	0
Investigations	Staphylococcus test positive	1	1	0
Investigations	Urine analysis normal	1	1	0
Metabolism and nutrition disorders	Lactose intolerance	1	1	0
Metabolism and nutrition disorders	Metabolic acidosis	1	1	0
Musculoskeletal and connective tissue disorders	Metatarsalgia	1	1	0
Musculoskeletal and connective tissue disorders	Osteoarthritis	1	1	0
Musculoskeletal and connective tissue disorders	Seronegative arthritis	1	1	0
Musculoskeletal and connective tissue disorders	Tenosynovitis stenosans	1	1	1
Musculoskeletal and connective tissue disorders	Vertebral foraminal stenosis	1	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	1	1	0
Nervous system disorders	Basilar artery aneurysm	1	0	0
Nervous system disorders	Dyspraxia	1	1	0
Nervous system disorders	Motor dysfunction	1	1	0
Nervous system disorders	Parkinson's disease	1	0	0
Product issues	Product label issue	1	1	0
Product issues	Thrombosis in device	1	1	0
Psychiatric disorders	Delusional disorder, unspecified type	1	1	0
Psychiatric disorders	Head banging	1	1	0
Psychiatric disorders	Panic disorder	1	1	0
Renal and urinary disorders	Renal tubular necrosis	1	1	0
Reproductive system and breast disorders	Abnormal uterine bleeding	1	1	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Reproductive system and breast disorders	Ejaculation disorder	1	1	0
Reproductive system and breast disorders	Premenstrual dysphoric disorder	1	1	0
Respiratory, thoracic and mediastinal disorders	Acute pulmonary oedema	1	1	0
Respiratory, thoracic and mediastinal disorders	Lower respiratory tract congestion	1	1	0
Skin and subcutaneous tissue disorders	Nodular rash	1	1	0
Skin and subcutaneous tissue disorders	Pemphigoid	1	1	0
Surgical and medical procedures	Endotracheal intubation	1	1	0
Vascular disorders	Peripheral venous disease	1	1	0
Vascular disorders	Vein discolouration	1	1	0
Vascular disorders	Vein disorder	1	1	0
Blood and lymphatic system disorders	Acquired haemophilia	1	1	0
Blood and lymphatic system disorders	Platelet destruction increased	1	1	0
Cardiac disorders	Atrial enlargement	1	1	0
Cardiac disorders	Bundle branch block left	1	1	0
Cardiac disorders	Right ventricular hypertrophy	1	1	1
Congenital, familial and genetic disorders	Vascular malformation	1	1	0
Ear and labyrinth disorders	Sudden hearing loss	1	1	0
Endocrine disorders	Secondary hypothyroidism	1	1	0
Eye disorders	Central vision loss	1	1	0
Eye disorders	Metamorphopsia	1	1	0
Eye disorders	Orbital myositis	1	1	0
Eye disorders	Orbital swelling	1	1	0
Gastrointestinal disorders	Gastrointestinal hypermotility	1	1	0
Gastrointestinal disorders	Oesophageal rupture	1	1	0
General disorders and administration site conditions	Administration site indentation	1	1	0
General disorders and administration site conditions	Injection site joint erythema	1	1	0
General disorders and administration site conditions	Pre-existing condition improved	1	1	0
General disorders and administration site conditions	Soft tissue inflammation	1	1	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Hepatobiliary disorders	Hepatorenal failure	1	1	1
Immune system disorders	Immunisation reaction	1	1	0
Infections and infestations	Campylobacter gastroenteritis	1	1	0
Infections and infestations	Infected cyst	1	1	0
Infections and infestations	Ophthalmic herpes simplex	1	1	0
Infections and infestations	Pneumonia streptococcal	1	1	0
Infections and infestations	Varicella post vaccine	1	1	0
Injury, poisoning and procedural complications	Toxicity to various agents	1	1	1
Investigations	Creatine urine abnormal	1	1	0
Investigations	CSF white blood cell count decreased	1	1	0
Investigations	Gastrointestinal stoma output abnormal	1	0	0
Investigations	Heart rate variability increased	1	0	0
Investigations	Hormone level abnormal	1	1	0
Investigations	Tryptase increased	1	1	0
Metabolism and nutrition disorders	Alcohol intolerance	1	1	0
Metabolism and nutrition disorders	Hypervolaemia	1	1	0
Musculoskeletal and connective tissue disorders	Enthesopathy	1	1	0
Musculoskeletal and connective tissue disorders	Facial asymmetry	1	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Brain neoplasm	1	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Melanocytic naevus	1	1	0
Nervous system disorders	Colloid brain cyst	1	1	0
Nervous system disorders	Facial neuralgia	1	1	0
Nervous system disorders	Hypertonia	1	1	0
Nervous system disorders	Infant irritability	1	1	0
Nervous system disorders	Trigeminal nerve disorder	1	1	0
Product issues	Device dislocation	1	1	0
Psychiatric disorders	Breathing-related sleep disorder	1	1	0
Psychiatric disorders	Somatic symptom disorder	1	1	0
Renal and urinary disorders	Anuria	1	1	0
Reproductive system and breast disorders	Galactorrhoea	1	1	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Respiratory, thoracic and mediastinal disorders	Agonal respiration	1	1	1
Respiratory, thoracic and mediastinal disorders	Nasal polyps	1	1	0
Respiratory, thoracic and mediastinal disorders	Obstructive airways disorder	1	1	0
Skin and subcutaneous tissue disorders	Acne cystic	1	1	0
Skin and subcutaneous tissue disorders	Acute febrile neutrophilic dermatosis	1	1	0
Skin and subcutaneous tissue disorders	Follicular mucinosis	1	1	0
Skin and subcutaneous tissue disorders	Milia	1	1	0
Skin and subcutaneous tissue disorders	Nail discolouration	1	1	0
Skin and subcutaneous tissue disorders	Palmar-plantar erythrodysaesthesia syndrome	1	1	0
Skin and subcutaneous tissue disorders	Skin necrosis	1	1	0
Surgical and medical procedures	Cardioversion	1	1	0
Surgical and medical procedures	Hip arthroplasty	1	1	0
Surgical and medical procedures	Tooth extraction	1	1	0
Vascular disorders	Haemodynamic instability	1	1	1
Vascular disorders	Hyperaemia	1	1	0
Vascular disorders	Neurogenic shock	1	1	0
Blood and lymphatic system disorders	Thymus disorder	1	1	0
Ear and labyrinth disorders	Deafness transitory	1	1	0
Ear and labyrinth disorders	Paraesthesia ear	1	1	0
Eye disorders	Opsoclonus myoclonus	1	0	1
Eye disorders	Vitreous adhesions	1	1	0
Gastrointestinal disorders	Oral mucosal eruption	1	1	0
General disorders and administration site conditions	Vaccination site discomfort	1	1	0
General disorders and administration site conditions	Vaccination site induration	1	1	0
Hepatobiliary disorders	Hepatic vein embolism	1	1	0
Immune system disorders	Cytokine release syndrome	1	1	0
Immune system disorders	Type III immune complex mediated reaction	1	1	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Infections and infestations	Aerococcus urinae infection	1	1	0
Infections and infestations	Cavernous sinus thrombosis	1	1	0
Infections and infestations	Endocarditis meningococcal	1	1	0
Infections and infestations	Neutropenic sepsis	1	1	0
Infections and infestations	Paronychia	1	1	0
Infections and infestations	Pharyngitis bacterial	1	1	0
Injury, poisoning and procedural complications	Chest crushing	1	1	0
Injury, poisoning and procedural complications	Epicondylitis	1	1	0
Injury, poisoning and procedural complications	Exposure to SARS-CoV-2	1	0	0
Injury, poisoning and procedural complications	Intentional overdose	1	1	1
Injury, poisoning and procedural complications	Recall phenomenon	1	1	0
Injury, poisoning and procedural complications	Rib fracture	1	1	0
Injury, poisoning and procedural complications	Skull fracture	1	1	0
Injury, poisoning and procedural complications	Stress fracture	1	1	0
Injury, poisoning and procedural complications	Subcutaneous haematoma	1	1	0
Injury, poisoning and procedural complications	Tooth injury	1	1	0
Investigations	Blood carbon monoxide decreased	1	1	0
Investigations	Blood sodium increased	1	1	0
Investigations	Red blood cell sedimentation rate abnormal	1	1	0
Metabolism and nutrition disorders	Hyponatraemic syndrome	1	1	0
Metabolism and nutrition disorders	Ketosis	1	1	0
Metabolism and nutrition disorders	Salt craving	1	1	0
Musculoskeletal and connective tissue disorders	Antisynthetase syndrome	1	1	0
Musculoskeletal and connective tissue disorders	Arthritis allergic	1	1	0
Musculoskeletal and connective tissue disorders	Still's disease	1	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Hypergammaglobulinaemia benign monoclonal	1	1	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pituitary tumour	1	1	0
Nervous system disorders	Arachnoiditis	1	1	0
Nervous system disorders	Carotid artery stenosis	1	1	0
Nervous system disorders	Cerebral small vessel ischaemic disease	1	1	0
Nervous system disorders	Tongue paralysis	1	1	0
Pregnancy, puerperium and perinatal conditions	Ectopic pregnancy with contraceptive device	1	1	0
Product issues	Product lot number issue	1	1	0
Psychiatric disorders	Fear of injection	1	1	0
Psychiatric disorders	Sleep terror	1	1	0
Reproductive system and breast disorders	Breast engorgement	1	1	0
Reproductive system and breast disorders	Genital pain	1	1	0
Reproductive system and breast disorders	Ovarian enlargement	1	1	0
Reproductive system and breast disorders	Ovarian failure	1	1	0
Respiratory, thoracic and mediastinal disorders	Cough decreased	1	1	0
Skin and subcutaneous tissue disorders	Dermatitis psoriasiform	1	1	0
Skin and subcutaneous tissue disorders	Lichen planus	1	1	0
Skin and subcutaneous tissue disorders	Panniculitis	1	1	0
Skin and subcutaneous tissue disorders	Skin depigmentation	1	1	0
Skin and subcutaneous tissue disorders	Skin disorder	1	1	0
Surgical and medical procedures	Emergency care	1	1	0
Vascular disorders	Carotidynia	1	1	0
Vascular disorders	Coeliac artery occlusion	1	1	0
Vascular disorders	Internal haemorrhage	1	1	0
Vascular disorders	Phlebitis superficial	1	1	0
Vascular disorders	Venous thrombosis limb	1	1	0
Cardiac disorders	Acute cardiac event	1	1	1
Cardiac disorders	Cardiovascular symptom	1	1	0
Cardiac disorders	Pericardial haemorrhage	1	1	1

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Congenital, familial and genetic disorders	Factor V Leiden mutation	1	1	0
Congenital, familial and genetic disorders	Haemophilia	1	1	0
Eye disorders	Eye paraesthesia	1	1	0
Eye disorders	Lagophthalmos	1	1	0
Eye disorders	Ophthalmoplegia	1	1	0
Gastrointestinal disorders	Abdominal symptom	1	1	0
Gastrointestinal disorders	Chronic gastritis	1	1	0
Gastrointestinal disorders	Defaecation urgency	1	1	0
Gastrointestinal disorders	Diverticular perforation	1	1	0
Gastrointestinal disorders	Intra-abdominal haemorrhage	1	1	0
Gastrointestinal disorders	Levator syndrome	1	1	0
Gastrointestinal disorders	Oesophageal perforation	1	1	0
Gastrointestinal disorders	Oral papule	1	1	0
General disorders and administration site conditions	Granuloma	1	1	0
General disorders and administration site conditions	Injury associated with device	1	1	0
General disorders and administration site conditions	Mucosa vesicle	1	1	0
General disorders and administration site conditions	Vaccination site nodule	1	1	0
Immune system disorders	Autoimmune disorder	1	1	0
Infections and infestations	Breast abscess	1	1	1
Infections and infestations	Epididymitis	1	1	0
Infections and infestations	Haematoma infection	1	1	0
Infections and infestations	Klebsiella infection	1	1	0
Infections and infestations	Tinea infection	1	1	0
Injury, poisoning and procedural complications	Burn oesophageal	1	1	0
Injury, poisoning and procedural complications	Traumatic intracranial haemorrhage	1	0	1
Investigations	Activated partial thromboplastin time	1	1	0
Investigations	Blood urea increased	1	1	0
Investigations	Echocardiogram abnormal	1	1	0
Investigations	Electrocardiogram ST segment depression	1	1	0
Investigations	Immunology test	1	1	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Investigations	Interleukin level	1	1	0
Investigations	Oxygen saturation immeasurable	1	1	0
Investigations	White blood cell count abnormal	1	1	0
Metabolism and nutrition disorders	Metabolic disorder	1	1	0
Metabolism and nutrition disorders	Oligodipsia	1	1	0
Metabolism and nutrition disorders	Vitamin B12 deficiency	1	1	0
Musculoskeletal and connective tissue disorders	Tendon disorder	1	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Metastasis	1	1	0
Nervous system disorders	Carotid artery dissection	1	1	0
Nervous system disorders	Immune-mediated encephalitis	1	1	0
Nervous system disorders	Vibratory sense increased	1	1	0
Product issues	Product expiration date issue	1	1	0
Psychiatric disorders	Claustrophobia	1	1	0
Psychiatric disorders	Mental fatigue	1	1	0
Psychiatric disorders	Tic	1	1	0
Renal and urinary disorders	Bladder disorder	1	1	0
Renal and urinary disorders	Bladder stenosis	1	1	0
Renal and urinary disorders	Ureterolithiasis	1	1	0
Renal and urinary disorders	Urge incontinence	1	1	0
Reproductive system and breast disorders	Breast disorder female	1	1	0
Reproductive system and breast disorders	Nipple swelling	1	1	0
Respiratory, thoracic and mediastinal disorders	Increased viscosity of upper respiratory secretion	1	1	0
Respiratory, thoracic and mediastinal disorders	Pulmonary arterial hypertension	1	1	0
Respiratory, thoracic and mediastinal disorders	Respiratory tract oedema	1	1	0
Skin and subcutaneous tissue disorders	Rash maculovesicular	1	1	0
Surgical and medical procedures	Cyst removal	1	1	0
Surgical and medical procedures	Injection	1	1	0
Vascular disorders	Arterial rupture	1	1	0
Vascular disorders	Blood pressure inadequately controlled	1	1	0
Vascular disorders	Varicophlebitis	1	1	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Blood and lymphatic system disorders	Macrocytosis	1	1	0
Blood and lymphatic system disorders	Splenic thrombosis	1	1	1
Cardiac disorders	Giant cell myocarditis	1	1	0
Congenital, familial and genetic disorders	Ehlers-Danlos syndrome	1	1	0
Endocrine disorders	Thyroid pain	1	1	0
Eye disorders	Optic nerve sheath haemorrhage	1	1	0
Eye disorders	Vitritis	1	1	0
Gastrointestinal disorders	Salivary duct obstruction	1	1	0
Gastrointestinal disorders	Salivary gland mucocoele	1	1	0
General disorders and administration site conditions	Injection site pallor	1	1	0
General disorders and administration site conditions	Nonspecific reaction	1	1	0
Immune system disorders	Cytokine storm	1	1	0
Infections and infestations	Candida cervicitis	1	1	0
Infections and infestations	Cholecystitis infective	1	1	0
Infections and infestations	Cytomegalovirus infection	1	1	0
Infections and infestations	Endometritis	1	1	0
Infections and infestations	Eyelid infection	1	1	0
Infections and infestations	Hepatic infection	1	1	0
Infections and infestations	Laryngopharyngitis	1	1	0
Infections and infestations	Otitis externa	1	1	0
Infections and infestations	Sinusitis bacterial	1	1	0
Investigations	Albumin urine present	1	1	0
Investigations	Blood immunoglobulin E abnormal	1	1	0
Investigations	Blood pressure diastolic	1	1	0
Investigations	Carotid pulse abnormal	1	1	0
Investigations	Cortisol decreased	1	1	0
Investigations	C-reactive protein abnormal	1	1	0
Investigations	Haemoglobin abnormal	1	1	0
Investigations	PO2 abnormal	1	1	0
Investigations	Skin temperature	1	1	0
Musculoskeletal and connective tissue disorders	Myalgia intercostal	1	1	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer metastatic	1	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Metastases to liver	1	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	1	1	0
Nervous system disorders	Burning feet syndrome	1	1	0
Nervous system disorders	Burning sensation mucosal	1	1	0
Nervous system disorders	Carotid artery aneurysm	1	1	0
Nervous system disorders	Chorea	1	1	0
Nervous system disorders	Demyelinating polyneuropathy	1	1	1
Nervous system disorders	Hyporesponsive to stimuli	1	1	0
Nervous system disorders	Neuralgic amyotrophy	1	1	0
Nervous system disorders	Noninfective encephalitis	1	1	0
Nervous system disorders	Numb chin syndrome	1	1	0
Nervous system disorders	Quadrantanopia	1	1	0
Nervous system disorders	Radial nerve palsy	1	1	0
Nervous system disorders	Ulnar nerve palsy	1	1	0
Psychiatric disorders	Intrusive thoughts	1	1	0
Psychiatric disorders	Middle insomnia	1	1	0
Psychiatric disorders	Paranoia	1	1	0
Renal and urinary disorders	Bladder dysfunction	1	1	0
Renal and urinary disorders	Nephrotic syndrome	1	1	0
Renal and urinary disorders	Renal cyst	1	1	0
Reproductive system and breast disorders	Ejaculation failure	1	1	0
Reproductive system and breast disorders	Menometrorrhagia	1	1	0
Reproductive system and breast disorders	Premenstrual syndrome	1	1	0
Reproductive system and breast disorders	Vaginal cyst	1	1	0
Respiratory, thoracic and mediastinal disorders	Choking	1	1	1
Respiratory, thoracic and mediastinal disorders	Nasal oedema	1	0	0
Respiratory, thoracic and mediastinal disorders	Reflux laryngitis	1	1	0
Respiratory, thoracic and mediastinal disorders	Respiratory acidosis	1	1	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Skin and subcutaneous tissue disorders	Acute generalised exanthematous pustulosis	1	1	0
Skin and subcutaneous tissue disorders	Circumoral oedema	1	1	0
Skin and subcutaneous tissue disorders	Dermatitis exfoliative generalised	1	1	0
Skin and subcutaneous tissue disorders	Guttate psoriasis	1	1	0
Skin and subcutaneous tissue disorders	Lichen sclerosus	1	1	0
Skin and subcutaneous tissue disorders	Palpable purpura	1	1	0
Surgical and medical procedures	Interchange of vaccine products	1	0	0
Vascular disorders	Angiopathy	1	1	0
Vascular disorders	Capillary fragility	1	1	0
Vascular disorders	Ischaemic limb pain	1	1	0
Vascular disorders	Peripheral artery stenosis	1	1	0
Vascular disorders	Venous occlusion	1	1	0
Vascular disorders	Vessel perforation	1	1	0

Footnotes

ⁱ A description of what, in general terms, was affected by the adverse event, as described by the Medical Dictionary for Regulatory Activities MedDRA (for example 'cardiac disorders')

ⁱⁱ A description of the adverse event as defined by MedDRA; these adverse events are grouped by system organ class. You can use the MedlinePlus medical dictionary <<http://www.nlm.nih.gov/medlineplus/mplusdictionary.html>> to look up terms.

ⁱⁱⁱ The number of cases for which each type of adverse event was reported

^{iv} Results show where a medicine is the only medicine suspected to be related to the adverse event

^v These reports of death may or may not have been the result of taking a medicine